IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH, a Delaware corporation,)
Plaintiff,)
VS.) C.A. No. 06-663-SLR
CORDIS CORPORATION, a Florida corporation,) REDACTED) PUBLIC VERSION
Defendant.)))

APPENDIX (VOLUME I - PLEADINGS) TO PLAINTIFF WYETH'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANT CORDIS CORPORATION'S "MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) OR, IN THE ALTERNATIVE, TO DISMISS OR STAY THIS ACTION PENDING RESOLUTION OF THE CO-PENDING ACTION IN THE DELAWARE COURT OF CHANCERY"

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VOLUME I TABLE OF EXHIBITS

Exhibit	Description
	Description
1	Cordis Corporation's Answer and Affirmative Defenses to Plaintiffs' First Amended Complaint, <i>Entenberg v. Cordis Corp.</i> , No. 06-61554 (S.D. Fl. Oct. 16, 2006)
2	Answer and Counterclaim of Defendant Cordis Corp. to Plaintiff's First Amended Complaint and Defendant's Demand for Jury Trial, <i>Spectralytics Inc. v. Cordis Corp.</i> , No. 05-cv-1464 (JRT/FLN) (D. Minn. Aug. 17, 2006)
3	First Amended Complaint, Spectralytics Inc. v. Cordis Corp., No. 05-cv-1464 (JRT/FLN) (D. Minn. Aug. 3, 2006)
4	Answer and Counterclaim of Defendant Cordis Corp., Spectralytics Inc. v. Cordis Corp., No. 05-cv-1464 (JRT/FLN) (D. Minn. Dec. 21, 2005)
5	Complaint, Spectralytics Inc. v. Cordis Corp., No. 05-cv-1464 (JRT/FLN) (D. Minn. July 21, 2005)
6	Answer of Defendant Cordis Corporation, <i>Conrad v. Cordis Corp.</i> , No 05-351 (E.D. Ky. Aug. 29, 2005)
7	Notice of Removal, Cassino v. Johnson & Johnson, No. 05-571 (D. Co. Mar. 28, 2005)
8	Notice of Removal, McConnell v. Cordis Corp., No. 04 2989 DV (W.D. Tenn. Dec. 3, 2004)
9	Answer and Affirmative Defenses of Cordis Corporation, <i>McConnell v. Cordis Corp.</i> , No. 04 2989 DV (W.D. Tenn. Dec. 3, 2004)
10	Notice of Removal, <i>Tantillo v. Cordis Corp.</i> , No. 04-2005 (E.D. La. July 16, 2004)
11	Defendant Cordis Corporation's Answer to Plaintiff Stratienko's Amended Complaint, Stratienko v. Cordis Corp., No. 02-005 (E.D. Tenn. Apr. 30, 2003)
12	Answer, Arlaine & Gina Rockey, Inc. v. Cordis Corp., No. 02-022555 (S.D. Fl. Oct. 1, 2002)
13	Answer, Kan v. Cordis Corp., No. 02-0959 (N.D. Al. June 7, 2002)

Exhibit	Description
14	Complaint, Kan v. Cordis Corp., No. 02-0959 (N.D. Al. Apr. 17, 2002)
15	Defendant Cordis Corporation's Answer to Plaintiff Stratienko's Complaint, Stratienko v. Cordis Corp., No. 02-005 (E.D. Tenn. Jan. 21, 2002)
16	Cordis Corporation's Answer and Affirmative Defenses to Plaintiff's Complaint, <i>Tietjen v. Cordis Corp.</i> , No. 05-022711 CA 22 (Fla. Cir. Ct. 11th, Dec. 12, 2005) (Bates # CWY000809 - 821)
17	Answer and Affirmative Defenses of Johnson & Johnson and Cordis Corporation, <i>Clay-Taylor v. Hays, et al.</i> , No. 251-04-988 (Miss. Cir. Hinds Co. Dec. 27, 2004) (Bates # CWY000834 - 845)
18	Defendant's Answer and Affirmative Defenses, <i>Paris v. Cordis Corp.</i> , No. 04-18851 CA 13 (Fla. Cir. Ct. 11th, Oct. 13, 2004) (Bates # CWY000800 - 808)
19	Answering Brief in Opposition to Wyeth's Motion to Dismiss or, In the Alternative, To Stay This Action (Chancery Court, Jan. 11, 2007) (without Exhibits) (Redacted Version)
20	Wyeth's Brief in Support of its Motion to Dismiss, or, In the Alternative, to Stay, This Action (Chancery Court, Dec. 5, 2006) (without Exhibits) (Redacted Version)

EXHIBIT 1

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UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO.:06-61554-CIV-LENARD/TORRES

HERBERT ENTENBERG and BARBARA ENTENBERG,

Plaintiffs,

v,

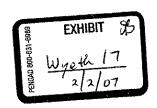
CORDIS CORPORATION, a Florida Corporation; and JOHNSON & JOHNSON, a foreign corporation,

Defendants

CORDIS CORPORATION'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Defendant, Cordis Corporation ("Cordis"), answers Plaintiffs' First Amended Complaint (the "Amended Complaint") as follows. Any allegation contained in the Amended Complaint not expressly and specifically admitted by Cordis is hereby denied.

- 1. Paragraph 1 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Amended Complaint.
- 2. Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Amended Complaint.
- 3. Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Amended Complaint.



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- 4. In response to paragraph 4 of the Amended Complaint, Cordis admits that it is a Florida corporation with its principal place of business in Miami Lakes, Florida.
- 5. In response to paragraph 5 of the Amended Complaint, Cordis admits that, upon information and belief, Johnson & Johnson Company is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Cordis denies the remaining allegations in paragraph 5.
- 6. In response to paragraph 6 of the Amended Complaint, Cordis admits that it is a separately operated and managed subsidiary of Johnson & Johnson Company. Defendants deny the remaining allegations contained in paragraph 6 of Plaintiffs' Amended Complaint.
- 7. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in paragraph 7 of Plaintiffs' Amended Complaint.

GENERAL ALLEGATIONS

- 8. Cordis reasserts and incorporates herein by reference its answers to paragraphs 1 through 7 of the Amended Complaint as if fully set forth herein.
- 9. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in paragraph 9 of the Amended Complaint.
- 10. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraph 10 of Plaintiffs' Amended Complaint. Cordis affirmatively states that it marketed, distributed, and sold the Cypher® Sirolimus-Eluting Coronary Stent ("Cypher® Stent") for use by physicians pursuant to the Premarket Approval granted by the Federal Food and Drug Administration ("FDA").

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11. In response to paragraph 11 of the Amended Complaint, Cordis states that the Cypher® Stent is a safe and effective treatment for certain cardiac conditions as determined by the patient's treating physician. Cordis denies the remaining allegations in paragraph 11.

CLASS ACTION ALLEGATIONS

12. Paragraph 12 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis only admits that Plaintiffs bring this case as a class action under Rule 1.200(b)(3) of the Florida Rules of Civil Procedure. Cordis specifically denies that this case is proper for class certification under Rule 1.220(b)(3) or any other rule.

I. SIZE AND DEFINITION OF THE CLASS

- 13. Cordis denies the allegations contained in paragraph 13 of the Amended Complaint. Cordis specifically denies that this case is proper for class certification and specifically denies that the purported class is or can be identified.
- 14. Paragraph 14 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordís specifically denies that this case is proper for class certification and specifically denies that the purported class is or can be identified.
- 15. In response to paragraph 15 of the Amended Complaint, Cordis admits that the Cypher® Stent has been used to successfully treat hundreds of thousands of patients. Cordis denies the remaining allegations in Paragraph 15 of the Complaint and specifically denies that the purported class is or can be identified.

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II. COMMONALITY

16. Cordis denies the allegations contained in paragraph 16, including subparts A through F, of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.

III. TYPICALITY

- 17. Cordis denies the allegations contained in paragraph 17 of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.
- 18. Cordis denies the allegations contained in paragraph 18 of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.

IV. ADEQUACY OF REPRESENTATION

- 19. Cordis denies the allegations contained in paragraph 19 of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.
- 20. Cordis denies the allegations contained in paragraph 20 of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.
- 21. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in paragraph 21 of the Amended Complaint.
- 22. In response to Paragraph 22 of the Amended Complaint, upon information and belief, Cordis denies that Plaintiffs have no conflicts with Class Members. Cordis is without

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knowledge as to the remaining allegations contained in paragraph 22 of Plaintiffs' Amended Complaint and therefore, denies the same.

V. REQUIREMENTS OF RULE 1.220(b)(3)

23. Cordis denies the allegations in paragraph 23, including subparts A and B, of the Amended Complaint and specifically denies that Plaintiffs can establish any of the prerequisites for maintaining this action as a class action.

COUNT I NEGLIGENCE CLAIM AGAINST CORDIS

- 24. Cordis reasserts and incorporates herein by reference its answers to paragraphs 1 through 23 of the Amended Complaint as if fully set forth herein.
- 25. In response to paragraph 25 of the Amended Complaint, Cordis admits that it designed, manufactured, marketed, distributed, tested, inspected, and sold the Cypher® Stent for use by physicians pursuant to the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in paragraph 25.
- 26. Paragraph 26 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis states that it complied with all legal duties.
- 27. Cordis denies the allegations in paragraph 27, including subparts A through E, of the Amended Complaint
 - 28. Cordis denies the allegations in paragraph 28 of the Amended Complaint.

COUNT II STRICT LIABILITY CLAIM AGAINST CORDIS

29. Cordis reasserts and incorporates herein by reference its answers to paragraphs 1 through 28 of the Amended Complaint as if fully set forth herein.

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- 30. In response to paragraph 30 of the Amended Complaint, Cordis admits that it designed, manufactured, marketed, distributed, tested, inspected, and sold the Cyper® Stent for use by physicians pursuant to the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in paragraph 30 of the Amended Complaint.
- 31. In response to paragraph 31 of the Amended Complaint, Cordis admit that the Cypher® Stent is a safe and effective treatment for certain cardiac conditions as determined by the patient's treating physician. Cordis denies the remaining allegations in paragraph 31 of the Amended Complaint.
- 32. In response to paragraph 32 of the Amended Complaint, Cordis admits that it designed, manufactured, marketed, distributed, tested, inspected, and sold the Cyper® Stent for use by physicians pursuant to the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in paragraph 32 of the Amended Complaint.
- 33. Cordis lacks knowledge or information sufficient to form a belief as to the truth of as to the allegations in paragraph 33 of the Amended Complaint.
- 34. Cordis denies the allegations in paragraph 34, including subparts A through D, of the Amended Complaint.
 - 35. Cordis denies the allegations in paragraph 35 of the Amended Complaint.

COUNT III <u>VIOLATION OF SECTIONS 501.201 ET. SEQ. FLORIDA'S DECEPTIVE AND UNFAIR TRADE PRACTICES ACT AGAINST CORDIS</u>

36. In response to the first paragraph numbered 36, Cordis reasserts and incorporates herein by reference its answers to paragraph 1 through 35 of the Amended Complaint as if fully set forth herein.

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- 36. The second paragraph numbered 36 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 36 of the Amended Complaint.
- 37. Paragraph 37 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Amended Complaint.
- 38. Paragraph 38 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38 of the Amended Complaint.
- 39. Paragraph 39 of the Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Cordis denies the allegations in paragraph 39 of the Amended Complaint.
 - 40. Cordis denies the allegations in paragraph 40 of the Amended Complaint.
 - 41. Cordis denies the allegations in paragraph 41 of the Amended Complaint.
 - 42. Cordis denies the allegations in paragraph 42 of the Amended Complaint.

COUNT IV NEGLIGENCE CLAIM AGAINST JOHNSON & JOHNSON

43. Cordis reasserts and incorporates herein by reference their answers to paragraphs 1 through 42 of the Amended Complaint as if fully set forth herein.

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- 44. The allegations contained in Paragraph 44 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 44 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 45. The allegations contained in Paragraph 45 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 45 is deemed to assert allegations against Cordis, Cordis states that it complied with all legal duties.
- 46. The allegations contained in Paragraph 46, including subparts A through E, of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 46 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 47. The allegations contained in Paragraph 47 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 47 is deemed to assert allegations against Cordis, Cordis denies these allegations.

COUNT V STRICT LIABILITY CLAIM AGAINST JOHNSON & JOHNSON

- 48. Cordis reasserts and incorporates herein by reference its answers to paragraphs 1 through 47 of the Amended Complaint as if fully set forth herein.
- 49. The allegations contained in Paragraph 49 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 49 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 50. The allegations contained in Paragraph 50 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 50 is deemed to assert allegations against Cordis, Cordis admits that the Cypher® Stent is a safe and effective

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treatment for certain cardiac conditions as determined by the patient's treating physicians. Cordis denies the remaining allegations in paragraph 50 of the Amended Complaint.

- 51. The allegations contained in Paragraph 51 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 51 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 52. The allegations contained in Paragraph 52 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 52 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 53. The allegations contained in Paragraph 53, including subparts A through D, of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 53 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 54. The allegations contained in Paragraph 54 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 54 is deemed to assert allegations against Cordis, Cordis denies these allegations.

COUNT VI <u>VIOLATION OF SECTIONS 501.201 ET. SEQ. FLORIDA'S DECEPTIVE AND UNFAIR</u> <u>TRADE PRACTICES ACT AGAINST JOHNSON & JOHNSON</u>

- 55. Cordis reasserts and incorporates herein by reference their answers to paragraphs1 through 54 of the Amended Complaint as if fully set forth herein.
- 56. The allegations contained in Paragraph 56 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. Paragraph 56 of the Amended Complaint also contains legal conclusions to which no response is required. To the extent Paragraph 56 is deemed to assert allegations against Cordis and a response is required, Cordis

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lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56 of the Amended Complaint.

- 57. The allegations contained in Paragraph 57 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. Paragraph 57 of the Amended Complaint also contains legal conclusions to which no response is required. To the extent Paragraph 57 is deemed to assert allegations against Cordis and a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 of the Amended Complaint.
- 58. The allegations contained in Paragraph 58 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. Paragraph 58 of the Amended Complaint also contains legal conclusions to which no response is required. To the extent Paragraph 58 is deemed to assert allegations against Cordis and a response is required, Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 of the Amended Complaint.
- 59. The allegations contained in Paragraph 59 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. Paragraph 59 of the Amended Complaint also contains legal conclusions to which no response is required. To the extent Paragraph 59 is deemed to assert allegations against Cordis and a response is required, Cordis denies these allegations.
- 60. The allegations contained in Paragraph 60 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 60 is deemed to assert allegations against Cordis, Cordis denies these allegations.

- 61. The allegations contained in Paragraph 61 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 61 is deemed to assert allegations against Cordis, Cordis denies these allegations.
- 62. The allegations contained in Paragraph 62 of the Amended Complaint are not directed to Cordis and, therefore, no response is required. To the extent Paragraph 62 is deemed to assert allegations against Cordis, Cordis denies these allegations.

COUNT VII DERIVATIVE CLAIM OF BARBARA ENTENBERG

- 63. Cordis reasserts and incorporates herein by reference their answers to paragraphs 1 through 62 of the Amended Complaint as if fully set forth herein.
 - 64. Cordis the allegations in paragraph 64 of Plaintiffs' Amended Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The claims asserted against Defendants are preempted either in whole or in part by the Federal Food, Drug & Cosmetic Act, the Medical Device Amendments thereto and/or any regulations promulgated thereunder, and the Supremacy Clause of Article VI of the United States Constitution and/or by the doctrine of deference to agency expertise.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' Amended Complaint, in whole or in part, fails to state a claim upon which relief may be granted individually and with respect to any class.

THIRD AFFIRMATIVE DEFENSE

The claims asserted in the Amended Complaint are barred, in whole or in part, by the applicable statute of limitations or statute of repose, and the doctrines of estoppel, waiver, laches, and unclean hands.

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FOURTH AFFIRMATIVE DEFENSE

Defendants did not make to Plaintiffs, nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent Plaintiffs rely on any theory of breach of warranty, any such claims are barred based upon Plaintiffs' lack of privity with Defendants and, additionally, because there was no reliance upon any warranties, if any, of Defendants.

FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs rely on any theory of breach of warranty, any such claims are barred in that Plaintiffs failed to provide Defendants with timely notice of any alleged breach of warranty. Defendants assert each and every defense and presumption available under the Uniform Commercial Code existing and which may arise in the future, as enacted in the State of Florida, and any other state whose law is deemed to apply in this case.

SIXTH AFFIRMATIVE DEFENSE

Defendants affirmatively state that Plaintiffs had full knowledge of the risks and possible adverse consequences pertaining to the medical treatment received and all or part of the injuries, damages and/or losses sustained by Plaintiffs, if any, arose from, and were caused by, risks of which Plaintiffs were so aware, and such risks were accepted and assumed by Plaintiffs and for that reason, any recovery against Defendants should be diminished, reduced, offset or barred, in accordance with the principles of informed consent.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained any of the injuries alleged in the Amended Complaint, which Defendants deny, there was an intervening and/or superseding cause or causes leading to such

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alleged injuries and, as such, any action or omission on the part of Defendants was not a proximate cause of Plaintiffs' alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained the injuries or incurred the expenses alleged in the Amended Complaint, which Defendants deny, such injuries and/or expenses resulted from pre-existing and/or unrelated medical, genetic and/or idiosyncratic conditions, diseases, or illness of Plaintiffs.

NINTH AFFIRMATIVE DEFENSE

Defendants state that any and all causes of action maintained by Plaintiffs against them based upon any alleged defect in the subject product are barred by the "learned intermediary" doctrine, or the "informed intermediary" doctrine, and/or the principles of §388 of the Restatement (Second) of Torts.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the methods, standards, and techniques utilized by Cordis in designing and manufacturing the product in question and in issuing warnings and instructions with respect to its use were in conformity with the generally recognized, reasonably available, and reliable state of knowledge in the field at the time the product was manufactured.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the Restatement (Second) of Torts: Product Liability § 402A and comments thereto and/or the Restatement (Third) of Torts: Products Liability § 6 and comments thereto.

TWELFTH AFFIRMATIVE DEFENSE

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Defendants were not under any legal obligation to give Plaintiffs notice or warnings about the use of the Cypher® Stent. All notices or warnings were properly given to physicians, the only persons authorized by law to prescribe the Cypher® Stent.

THIRTEENTH AFFIRMATIVE DEFENSE

The conduct of Defendants and the Cypher® Stent conformed to the state of the art at all relevant times.

FOURTEENTH AFFIRMATIVE DEFENSE

The Cypher® Stent was intended for and was sold to a knowledgeable and sophisticated user over whom Defendants had no control and who was fully informed of the risk and dangers, if any, associated with the Cypher® Stent and the precautions, if any, required to avoid those risks and dangers.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages were caused or contributed, directly and proximately, in whole or in part, by the negligence, fault, acts, breaches, omissions, or other wrongful conduct of Plaintiffs or others that are attributable to them, so that any recovery by Plaintiffs must be diminished by the degree such conduct is attributed to Plaintiffs in accordance with applicable law.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages were caused or contributed, directly and proximately, in whole or in part, by the negligence, fault, acts, breaches, omissions or other wrongful conduct of others so that any damages awarded in favor of Plaintiffs are subject to the comparative fault provisions of section 768.81, Florida Statutes, and Defendants cannot be liable for more than their proportionate share of any non-economic damages awarded. Further,

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pursuant to Fabre v. Marin, 623 So. 2d 1182 (Fla. 1993), any damages awarded to the Plaintiffs are subject to apportionment by the jury of the total fault of all participants.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs failed to exercise reasonable care and diligence to mitigate the injuries and damages, if any, alleged in the Amended Complaint, so that any recovery by Plaintiffs must be apportioned in direct proportion to such failure to mitigate in accordance with applicable laws.

EIGHTEENTH AFFIRMATIVE DEFENSE

Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor for the same injuries alleged in the Amended Complaint.

NINETEENTH AFFIRMATIVE DEFENSE

Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to a set-off for the total of all amounts paid to Plaintiffs from any collateral sources.

TWENTIETH AFFIRMATIVE DEFENSE

Only Florida residents or consumers are entitled to pursue claims under the Florida's Deceptive and Unfair Trade Practices Act.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs have failed to establish the requirements for a class action, including any requirement set forth pursuant to Fla. R. Civ. P. 1.220, et seq

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs lack standing to assert claims on behalf of purported absent class members.

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TWENTY-THIRD AFFIRMATIVE DEFENSE

Defendants reserve the right to assert other such defenses as may become available or appear during discovery proceedings in this case and hereby reserve the right to amend their answer to assert any such defenses.

DEMAND FOR JURY TRIAL

Defendant, Cordis Corporation demands a trial by jury on all issues so triable as a matter of right as to Cordis.

WHEREFORE, Defendant, Cordis, respectfully requests that the Plaintiffs' Amended Complaint be dismissed with prejudice at Plaintiffs' cost, that Defendant Cordis be awarded its costs and expenses, including reasonable attorneys' fees to the extent permitted by law, and for such further relief as this Court deems just and equitable.

/s/ NEVILLE M. LESLIE

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 16th day of October, 2006, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

/s/ NEVILLE M. LESLIE

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Service List

HERBERT ENTENBERG AND BARBARA ENTENBERG V. CORDIS CORPORATION AND JOHNSON & JOHNSON

CASE NO: 06-61554-CIV-LENARD/TORRES

UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF FLORIDA

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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

SPECTRALYTICS, INC.

Plaintiff,

Civil Action No. 05-1464 (PJS/RLE)

CORDIS CORPORATION and

NORMAN NOBLE, INC.

Defendants.

-and-

JURY TRIAL DEMANDED

CORDIS CORPORATION

Counterclaim Plaintiff,

٧.

SPECTRALYTICS, INC.

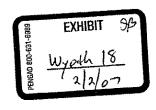
Counterclaim Defendant.

ANSWER AND COUNTERCLAIM OF DEFENDANT CORDIS CORPORATION TO PLAINTIFF'S FIRST AMENDED COMPLAINT AND DEFENDANT'S DEMAND FOR JURY TRIAL

Defendant/Counterclaim Plaintiff Cordis Corporation ("Cordis"), by its undersigned attorneys, for its reply to the claims asserted in Plaintiff's First Amended Complaint and for its counterclaim against Plaintiff/Counterclaim Defendant Spectralytics, Inc. ("Spectralytics"), alleges as follows:

Defendant admits upon information and belief that Spectralytics is a
 Minnesota corporation having a principal place of business in Minnesota and denies having

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knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1 of the First Amended Complaint.

- Defendant admits the allegations of paragraph 2 of the First Amended
 Complaint.
- 3. Defendant admits upon information and belief that Norman Noble, Inc. ("NNI") is an Ohio corporation and denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3 of the First Amended Complaint.
- 4. Defendant admits that this action purports to arise under the patent laws of the United States, Title 35 of the United States Code, for alleged infringement of United States

 Patent Nos. 6,114,653 (the "653 patent") and 5,852,277 (the "277 patent") as well as for misappropriation of trade secrets, and unfair competition.
- Defendant admits that Spectralytics alleges that this court has jurisdiction under 28 U.S.C. §§ 1331, 1332 and 1338(a).
- Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6 of the First Amended Complaint.
- Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 7 of the First Amended Complaint.
- 8. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 of the First Amended Complaint.
- 9. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 of the First Amended Complaint.

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- 10. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 of the First Amended Complaint.
- 11. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the First Amended Complaint.
- 12. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 of the First Amended Complaint.
- Defendant admits the allegations of paragraph 13 of the First Amended
 Complaint.
 - 14. Defendant admits that NNI laser cuts stents for sale by Cordis.
 - 15. Defendant admits that this is an action for patent infringement.
- 16. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 of the First Amended Complaint.
 - 17. Defendant denies the allegations of paragraph 17 of the Complaint.
 - 18. Defendant denies the allegations of paragraph 18 of the Complaint.
 - Defendant denies the allegations of paragraph 19 of the Complaint.
 - 20. Defendant denies the allegations of paragraph 20 of the Complaint.
 - 21. Defendant denies the allegations of paragraph 21 of the Complaint.
 - 22. Defendant admits that this is an action for patent infringement.
- 23. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint.
 - 24. Defendant denies the allegations of paragraph 24 of the Complaint.
 - 25. Defendant denies the allegations of paragraph 25 of the Complaint.
 - 26. Defendant denies the allegations of paragraph 26 of the Complaint.

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- 27. Defendant denies the allegations of paragraph 27 of the Complaint.
- 28. Defendant denies the allegations of paragraph 28 of the Complaint
- 29. Defendant admits that this is an action for misappropriation of trade secrets as against NNI only.
- 30. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30 of the First Amended Complaint.
- 31 Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31 of the First Amended Complaint.
- 32. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 32 of the First Amended Complaint.
- 33. Defendant admits that this is an action for unfair competition as against NNI only.
- 34. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34 of the First Amended Complaint.
- 35. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 35 of the First Amended Complaint.
- 36. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 36 of the First Amended Complaint.
- 37. Defendant denies having knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37 of the First Amended Complaint.

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AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

38. The '653 patent is invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.

SECOND AFFIRMATIVE DEFENSE

39. The '277 patent is invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.

THIRD AFFIRMATIVE DEFENSE

40. Defendant has not directly infringed any claim of the '653 patent, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

41. Defendant has not directly infringed any claim of the '277 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

42. Defendant has not contributorily infringed or induced infringement of any claim of the '653 patent.

SIXTH AFFIRMATIVE DEFENSE

43. Defendant has not contributorily infringed or induced infringement of any claim of the '277 patent.

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SEVENTH AFFIRMATIVE DEFENSE

44. Plaintiff is estopped from asserting that the Defendant has infringed the claims of the '653 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

EIGHTH AFFIRMATIVE DEFENSE

45. Plaintiff is estopped from asserting that the Defendant has infringed the claims of the '277 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

NINTH AFFIRMATIVE DEFENSE

46. Upon information and belief, the Plaintiff is barred, in whole or in part, from recovery for the alleged infringement by the Defendant by reason of Plaintiff's failure to comply with the requirements of 35 U.S.C. § 287.

COUNTERCLAIM

As and for its counterclaim against counterclaim-defendant Spectralytics, defendant and counterclaim-plaintiff Cordis alleges as follows:

47. Upon information and belief, Spectralytics is a corporation organized and existing under the laws of the State of Minnesota, having a place of business at 145 South 3d Street, Dassel, Minnesota 55325-0911

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- 48. Cordis is a corporation organized and existing under the laws of the State of Florida, having its principal places of business at 40 Technology Drive, Warren, New Jersey and at 14201 N.W. 60th Avenue, Miami Lakes, Florida.
- 49. This counterclaim arises under the Declaratory Judgment Act and the Patent Laws of the United States, more particularly under Title 28 U.S.C. §§ 2201 and 2202 and Title 35 U.S.C. §§ 100 et. seq., respectively. This court has jurisdiction under Title 28 U.S.C. §§ 1338 and 2201.
- 50. An actual and justiciable controversy exists between Cordis and Spectralytics as to the infringement and validity of the '653 and '277 patents, as evidenced, inter alia, by the Complaint and Answer in this action.
- 51. On information and belief, United States Letters Patent No. 6,114,653, entitled "Method of Cutting Hollow Workpieces with a Laser" and issued September 5, 2000, and United States Letters Patent No. 5,852,277, entitled "Laser Cutting Tool for Cutting Elongated Hollow Workpieces," and issued December 22, 1998, are invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.
- 52. Cordis has not directly infringed any claim of the '653 patent or the '277 patent, either literally or under the doctrine of equivalents.
- 53. Cordis has not contributorily infringed or induced infringement of any claim of the '653 patent or the '277 patent.
- 54. On information and belief, Spectralytics is estopped from asserting that Cordis has infringed the claims of the '653 patent due to the amendments of claims and

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arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

- On information and belief, Spectralytics is estopped from asserting that Cordis has infringed the claims of the '277 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.
- 56. Upon information and belief, Spectralytics is barred, in whole or in part, from recovery for the alleged infringement by Cordis by reason of Spectralytics' failure to comply with the requirements of 35 U.S.C. § 287.

WHEREFORE, Cordis prays for an adjudication against Spectralytics as follows:

- A. That Spectralytics' First Amended Complaint be dismissed with prejudice;
- B. That Spectralytics and all parties in active concert therewith be enjoined from asserting the '653 and '277 patents against Cordis;
 - That the claims of the '653 and '277 patents be declared invalid;
 - That the claims of the '653 and '277 patents be declared unenforceable;
- That the claims of the '653 and '277 patents be declared not infringed by
 Cordis;
- F. That this case be declared exceptional under 35 U.S.C. § 285, and that Cordis be awarded its reasonable attorney fees and expenses of litigation against Spectralytics;
 - G. That Cordis be awarded costs of this suit; and
- H. That Cordis be awarded such other and further relief as this Court shall deem just and proper.

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JURY DEMAND

Counterclaim Plaintiff Cordis hereby respectfully requests trial by jury on all

issues triable to a jury.

Dated: August 17, 2006

ANTHONY OSTLUND & BAER, P.A.

s/Courtland C. Merrill Joseph W. Anthony (#2832) Courtland C. Merrill (#311984) 3600 Wells Fargo Center 90 South Seventh Street Minneapolis, MN 55402 (612) 349-6969

Of Counsel:

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William E, Craco Paul A. Coletti **JOHNSON & JOHNSON** One Johnson & Johnson Plaza New Brunswick, New Jersey 08933

Attorneys for Defendant/Counterclaim Plaintiff Cordis Corporation

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

SPECTRALYTICS, INC.

Plaintiff,

Civil Action No. 05-1464 (PJS/RLE)

۲.

CORDIS CORPORATION and

NORMAN NOBLE, INC.

Defendants.

-and-

CORDIS CORPORATION

Counterclaim Plaintiff,

γ.

SPECTRALYTICS, INC.

Counterclaim Defendant.

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2006, I caused the following documents:

 Answer and Counterclaim of Defendant Cordis Corporation to Plaintiff's First Amended Complaint and Defendant's Demand for Jury Trial;

to be filed electronically with the Clerk of Court through ECF, and that ECF will send an enotice of electronic filing to the following:

Dennis C Bremer, dbremer a ccvl com; kpetersen a ccvl com; kpotniston a ccvl com
Alan G Carlson, acarlson a ccvl com; jshea a ccvl com, kpetersen a ccvl com
Philip P Caspers, pcaspers a ccvl com; jshea a ccvl com; kpetersen a ccvl com
Matthew J Goggin, mgoggin a ccvl com; jshea a ccvl com; kpetersen a ccvl com
Samuel A Hamer, shamer a ccvl com; jshea a ccvl com; a callerstrom a ccvl com
Brian W Hayes, bhaves a ccvl com; gbruns a ccvl com; a callerstrom a ccvl com
Deakin T Lauer, dlauer a ccvl com; kstalsholl a ccvl com
Russell J Rigby, mighy a ccvl com; dkoza a ccvl com; a callerstrom a ccvl com

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I further certify that I caused a copy of the foregoing documents and the notice of electronic filing to be mailed by first class mail, postage prepaid, to the following non-ECF participants:

N/A

Dated: August 17, 2006

ANTHONY OSTLUND & BAER, P.A.

By s/Courtland C. Merrill
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Courtland C. Merrill (#311984)
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New Brunswick, New Jersey 08933

Attorneys for Defendant/Counterclaim
Plaintiff Cordis Corporation

— Original Message—

From: ecf-notice@mnd.uscourts.gov [mailto:ecf-notice@mnd.uscourts.gov]

Sent: Thursday, August 17, 2006 5:58 PM

To: ecf-notice@mnd.uscourts.gov

Subject: Activity in Case 0:05-cv-01464-PJS-RLE Spectralytics, Inc. v. Cordis Corporation "Answer to

Amended Complaint*

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U.S. District Court

District of Minnesota

Notice of Electronic Filing

The following transaction was received on 8/17/2006 at 4:58 PM CDT and filed on 8/17/2006

Case Name:

Spectralytics, Inc. v. Cordis Corporation

Case Number:

0:05-cv-1464

Filer:

Cordis Corporation

Document Number: 31

Docket Text:

ANSWER to Amended Complaint (First), COUNTERCLAIM against Spectralytics, Inc. by Cordis Corporation, Cordis Corporation. (Attachments: # (1) Certificate of Service)(Merrill, Courtland)

The following document(s) are associated with this transaction:

Document description: Main Document

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1051215216 [Date=8/17/2006] [FileNumber=1098989-0] [4d140141d5dc02f97c3018f77f6fb95fd842e2285a0da12d2de8e067a5ba43c07f5 ebae9ca9aa45af9ceeeb1767dbdf383db92847bf8288d06df080af23e207c]]

Document description: Certificate of Service

Original filename:n/a

Electronic document Stamp:

[STAMP dcecfStamp_ID=1051215216 [Date=8/17/2006] [FileNumber=1098989-1] [4c61378555e6f84df3d055982de432ac34636cb797d2f93ed70a97e697d89bbb7ab ea150521a739e181f328b32c3c4daeaeb925c88ad65932f7aef23d472ee73]]

0:05-cv-1464 Notice will be electronically mailed to:

Joseph W Anthony janthony@aoblaw.com, lwilhelm@aoblaw.com; lmcnamara@aoblaw.com

Dennis C Bremer dbremer@ccvl.com, acallerstrom@ccvl.com, kjohnston@ccvl.com

Alan G Carlson acarlson@ccvl.com, jshea@ccvl.com; acallerstrom@ccvl.com

Philip P Caspers pcaspers@ccvl.com, jshea@ccvl.com; acallerstrom@ccvl.com

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Brian W Hayes bhayes@ccvl.com, gbruns@ccvl.com; acallerstrom@ccvl.com

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Deakin T Lauer dlauer@ccvl.com, dkoza@ccvl.com; acallerstrom@ccvl.com

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Russell J Rigby rrigby@ccvl.com, dkoza@ccvl.com; acallerstrom@ccvl.com

Michael J Timmons mjtimmons@pbwt.com, mcolitigation@pbwt.com

0:05-cv-1464 Notice will be delivered by other means to:

Paul-NA A. Coletti Not Admitted

EXHIBIT 3

Case 0:05-cv-01464-PJS-RLE Document 30 Filed 08/03/2006 Page 1 of 8

IN THE UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

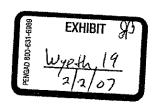
SPECTRALYTICS, INC.))
Plaintiff,))
VS.) Civil Action No. 05-1464 (PJS/RLE)
CORDIS CORPORATION and)))
NORMAN NOBLE, INC.)
Defendants.)
))
)

FIRST AMENDED COMPLAINT

Plaintiff SPECTRAlytics, Inc., for its First Amended Complaint, states as follows:

THE PARTIES

- 1. Plaintiff SPECTRAlytics, Inc. ("SPECTRAlytics") is incorporated under the laws of Minnesota and has a principal place of business at P.O. Box L, 145 South 3rd Street, Dassel, Minnesota 55325-0911. SPECTRAlytics is engaged in, among other things, the business of making surgical stents.
- 2. Upon information and belief, Defendant Cordis Corporation ("Cordis") is incorporated under the laws of the state of Florida and has a principal place of business at 14201 N.W. 60th Avenue, Miami Lakes, Florida 33014. Upon information and belief, Defendant Cordis is a wholly owned subsidiary of Johnson & Johnson and is engaged in the business of, among others, manufacturing and selling surgical stents.



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 Upon information and belief, Defendant Norman Noble, Inc. ("NNI") is incorporated under the laws of the state of Ohio and has a principal place of business at 1650 Collamer Road, Cleveland, Ohio 44110.

JURISDICTION

- 4. This is an action for patent infringement arising under the Acts of Congress relating to patents, 35 U.S.C. §§ 271, 281-285, as well as for misappropriation of trade secrets, and unfair competition.
 - 5. This Court has jurisdiction under 28 U.S.C. §§ 1331, 1332 and 1338(a).

GENERAL ALLEGATIONS

- 6. SPECTRAlytics is in the business of, among other things, laser cutting stents.

 SPECTRAlytics has been in the business of laser cutting stents for at least ten years.
- 7. SPECTRAlytics owns a variety of patents, trade secrets, and confidential information relating to its laser cutting business including, but not limited to, customer identities, revenue information, and the particular apparatuses and processes used to laser cut stents.
- 8. In the 1990s, NNI and SPECTRAlytics discussed the possibility of selling at least some of the business of SPECTRAlytics to NNI.
- 9. Upon information and belief, when SPECTRAlytics and NNI first entered such discussions, NNI was not in the business of laser cutting stents.
- 10. In connection with the discussions between the companies, NNI agreed that it would not use, and that it would keep confidential, certain information of SPECTRAlytics, including without limitation information concerning the processes and equipment used by SPECTRAlytics to laser cut stents. NNI signed a Confidentiality Agreement to that effect.
- 11. Relying on NNI's promise and agreement, SPECTRAlytics allowed NNI to enter and inspect SPECTRAlytics's premises in Minnesota, and SPECTRAlytics disclosed to NNI the processes and equipment used by SPECTRAlytics to laser cut stents. SPECTRAlytics would not

have permitted any inspection, or provided any such disclosure, absent NNI's agreement to keep such information confidential and to not use such information for its own benefit.

- 12. SPECTRAlytics and NNI never consummated an agreement pursuant to which NNI would acquire any part of the business of SPECTRAlytics.
- 13. NNI presently is in the business of, among other things, laser cutting stents. NNI supplies or sells such laser cut stents to persons including Cordis, a Johnson & Johnson company.
- 14. Upon information and belief, stents have been laser cut for sale by Cordis and by NNI on behalf of Cordis.

COUNT I—INFRINGEMENT OF U.S. PATENT NO. 5,852,277

- 15. This is an action for patent infringement. The foregoing paragraphs 1-14 are hereby incorporated by reference.
- 16. Plaintiff SPECTRAlytics is the owner of United States Patent 5,852,277 ("the '277 patent") entitled "Laser Cutting Tool for Cutting Elongated Hollow Workpieces," which duly and legally issued on December 22, 1998.
- 17. By its actions related to the use of the laser cutting tools to manufacture stents and the sales of stents manufactured by using laser cutting tools, Cordis has infringed the '277 patent (infringement defined to include direct, active inducement, and/or contributory infringement).
- 18. By its actions related to the use of the laser cutting tools to manufacture stents and the sales of stents manufactured by using laser cutting tools, NNI has infringed the '277 patent (infringement defined to include direct, active inducement, and/or contributory infringement).
- 19. Plaintiff has suffered irreparable harm due to Cordis's and NNI's infringement of the '277 patent and will continue to suffer irreparable harm in the future unless Cordis and NNI are enjoined from further infringement of the '277 patent.
 - 20. Cordis has been aware of the patents in suit and its infringement is willful.

21. NNI has been aware of the patents in suit and its infringement is willful.

COUNT II—INFRINGEMENT OF U.S. PATENT NO. 6,114,653

- 22. This is an action for patent infringement. The foregoing paragraphs 1-21 are hereby incorporated by reference.
- 23. Plaintiff SPECTRAlytics is the owner of United States Patent 6,114,653 ("the '653 patent") entitled "Method of Cutting Hollow Workpieces with a Laser," which duly and legally issued on September 5, 2000.
- 24. In addition, by its actions related to the use of laser cutting tools to manufacture stents and the sales of stents manufactured by using laser cutting tools, Cordis has infringed the '653 patent (infringement defined to include direct, active inducement, and/or contributory infringement).
- 25. In addition, by its actions related to the use of laser cutting tools to manufacture stents and the sales of stents manufactured by using laser cutting tools, NNI has infringed the '653 patent (infringement defined to include direct, active inducement, and/or contributory infringement).
- 26. In addition, Plaintiff has suffered irreparable harm due to Cordis's and NNI's infringement of the '653 patent and will continue to suffer irreparable harm in the future unless Cordis and NNI are enjoined from further infringement of the '653 patent.
 - 27. Cordis has been aware of the patents in suit and its infringement is willful.
 - 28. NNI has been aware of the patents in suit and its infringement is willful.

COUNT III—MISAPPROPRIATION OF TRADE SECRETS

- This is an action for misappropriation of trade secrets. The foregoing paragraphs1-14 are hereby incorporated by reference.
- 30. Upon information and belief, NNI misappropriated SPECTRAlytics trade secrets that NNI learned during the discussions and inspections referenced in paragraphs 8-11 in

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connection with laser cutting of stents. Those misappropriated trade secrets include, but may not be limited to, the SPECTRAlytics confidential and proprietary information concerning the processes and equipment it used to manufacture stents and it disclosed to NNI.

- 31. SPECTRAlytics recently learned of NNI's misappropriation.
- 32. SPECTRAlytics has suffered irreparable harm and damages as a result of NNI's misappropriation of trade secrets in an amount that exceeds \$75,000, and is likely to continue to suffer irreparable harm and damage unless NNI is permanently enjoined from disclosing and/or using for its own benefit the information it learned about SPECTRAlytics processes and equipment used to laser cut stents.

COUNT IV—UNFAIR COMPETITION

- 33. This is an action for unfair competition. The foregoing paragraphs 1-14 and 29-33 are hereby incorporated by reference.
- 34. Upon information and belief, NNI has unfairly competed with SPECTRAlytics by obtaining trade secret and other confidential information from NNI and using that information for NNI's commercial benefit and exploitation. For example, upon information and belief, NNI used that information to laser cut stents long before NNI otherwise would have been able to do so. As another example, upon information and belief, NNI used that information to obtain Cordis as a customer and interfere with SPECTRAlytics prospective business relationships.
 - 35. NNI's conduct constitutes unfair competition.
- 36. SPECTRAlytics has suffered irreparable harm and damages as a result of NNI's unfair competition in an amount that exceeds \$75,000, and is likely to continue to suffer irreparable harm and damage unless NNI is permanently enjoined from disclosing and/or using for its own benefit the information it learned about SPECTRAlytics processes and equipment used to laser cut stents.

37. Upon information and belief, NNI also has been unjustly enriched as a result of its unfair competition, and is likely to continue to be unjustly enriched unless it is preliminarily and permanently enjoined from further acts of unfair competition.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for the following relief:

- a. A judgment that Cordis and NNI have infringed U.S. Patent No. 5,852,277;
- b. A judgment that Cordis's and NNI's infringement of U.S. Patent No. 5,852,277 is willful;
- c. A preliminary injunction enjoining and restraining Cordis and NNI, their officers, directors, agents, servants, employees, attorneys and all others acting under or through them, directly or indirectly, from infringing U.S. Patent No. 5,852,277;
- d. A permanent injunction enjoining and restraining Cordis and NNI, their officers, directors, agents, servants, employees, attorneys and all others acting under or through them, directly or indirectly, from infringing U.S. Patent No. 5,852,277;
 - e. A judgment that Cordis and NNI have infringed U.S. Patent No. 6,114,653;
- f. A judgment that Cordis's and NNI's infringement of U.S. Patent No. 6,114,653 is willful;
- g. A preliminary injunction enjoining and restraining Cordis and NNI, their officers, directors, agents, servants, employees, attorneys and all others acting under or through them, directly or indirectly, from infringing U.S. Patent No. 6,114,653;
- h. A permanent injunction enjoining and restraining Cordis and NNI, their officers, directors, agents, servants, employees, attorneys and all others acting under or through them, directly or indirectly, from infringing U.S. Patent No. 6,114,653;

- i. A judgment and order requiring Cordis and NNI to pay all appropriate damages under 35 U.S.C. § 284, including treble damages if the infringement of the patents in suit is determined to be willful.
- j. A judgment and order requiring Cordis and NNI to pay the costs of this action, including all disbursements, and attorney fees if this case is exceptional as provided by 35 U.S.C. § 285, with prejudgment interest.
 - k. A judgment that NNI has misappropriated SPECTRAlytics's trade secrets.
 - 1. A judgment that NNI has unfairly competed with SPECTRAlytics.
- m. A permanent injunction enjoining and restraining NNI, its officers, directors, agents, servants, employees, attorneys and all others acting under or through it, directly or indirectly, from using SPECTRAlytics's confidential and proprietary information or otherwise misappropriating SPECTRAlytics's trade secrets.
- n. An order requiring NNI to deliver up to SPECTRAlytics for destruction all documents, electronic records, products, equipment, and other things that reflect, embody, or were created using SPECTRAlytics's trade secrets and other confidential and proprietary information.
- o. A judgment and order requiring NNI to pay all damages caused, and to disgorge all profits unjustly gained, by the misappropriation of trade secrets and unfair competition, with interest, as well as enhanced damages.
- p. A judgment and order directing NNI to pay the costs of this action (including all disbursements) and attorney fees, with interest.
 - q. Such other and further relief that this Court may deem just and equitable.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury of all issues triable by jury.

SPECTRAlytics, Inc.

By its attorneys,

Dated: August 3, 2006

s/ Dennis C. Bremer
Alan G. Carlson (MN #14,801)
Matthew J. Goggin (MN #210,705)
Dennis C. Bremer (MN #299,182)
CARLSON CASPERS VANDENBURGH
& LINDQUIST, P.A.
225 South Sixth Street, Suite 3200
Minneapolis, Minnesota 55402
Phone: (612) 436-9600
Fax: (612) 436-9605

EXHIBIT 4

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

SPECTRALYTICS, INC.

Plaintiff,

Civil Action No. 05-1464 (JRT/FLN)

CORDIS CORPORATION

Defendant.

-and-

CORDIS CORPORATION

Counterclaim Plaintiff,

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SPECTRALYTICS, INC.

Counterclaim Defendant.

ANSWER AND COUNTERCLAIM OF DEFENDANT CORDIS CORPORATION AND DEFENDANT'S DEMAND FOR JURY TRIAL

Defendant/Counterclaim Plaintiff Cordis Corporation ("Cordis"), by its undersigned attorneys, for its reply to the claims asserted in Plaintiff's Complainta nd for its counterclaim against Plaintiff/Counterclaim DefendantS pectralytics, Inc. (Spectralytics"), alleges as follows:

- 1. Defendant admits upon information and belief that Spectralytics is a Minnesota corporation having a principal place of business in Minnesota and denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1 of the Complaint.
 - 2. Defendant admits the allegations of paragraph 2 of the Complaint.

EXHIBIT QG

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- 3. Defendant admits that this action purports to arise under the patent laws of the United States, Title 35 of the United States Code, for alleged infringemento f United States Patent Nos. 6,114,653 (the "653 patent") and 5,852,277 (the "277 patent").
- Defendant admits that Spectralytics alleges that this court has jurisdiction under
 U.S.C. §§ 1331 and 1338(a).
- Defendant denies having knowledge or information sufficient to form a belief as
 to the truth of the allegations of paragraph 5 of the Complaint.
 - 6. Defendant denies the allegations of paragraph 6 of the Complaint.
 - 7. Defendant denies the allegations of paragraph 7 of the Complaint.
 - 8. Defendant denies the allegations of paragraph 8 of the Complaint.
- Defendant denies having knowledge or information sufficient to form a belief as
 to the truth of the allegations of paragraph 9 of the Complaint.
 - 10. Defendant denies the allegations of paragraph 10 of the Complaint.
 - 11. Defendant denies the allegations of paragraph 11 of the Complaint.
 - 12. Defendant denies the allegations of paragraph 12 of the Complaint.
- 13. Defendant denies that Plaintiff is entitled to any of the relief requested in the Complaint.
- 14. Except to the extente xpressly admitted herein, Defendant denies each and every allegation, matter, statement, and thing contained in the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

15. The '653 patent is invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.

SECOND AFFIRMATIVE DEFENSE

16. The '277 patent is invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101, 102, 103, and 112.

THIRD AFFIRMATIVE DEFENSE

17. Defendant has not directly infringed any claim of the '653 patent, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

18. Defendant has not directly infringed any claim of the '277 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

 Defendant has not contributorily infringed or induced infringement of any claim of the '653 patent.

SIXTH AFFIRMATIVE DEFENSE

of the '277 patent.

SEVENTH AFFIRMATIVE DEFENSE

21. Plaintiff is estopped from asserting that the Defendant has infringed the claims of the '653 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

EIGHTH AFFIRMATIVE DEFENSE

22. Plaintiff is estopped from asserting that the Defendant has infringed the claims of the '277 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

NINTH AFFIRMATIVE DEFENSE

23. Upon information and belief, the Plaintiff is barred, in whole or in part, from recovery for the alleged infringement by the Defendant by reason of Plaintiff's failure to comply with the requirements of 35 U.S.C. § 287.

COUNTERCLAIM

As and for its counterclaim against counterclaim-defendantS pectralytics, defendant and counterclaim-plaintiff Cordis alleges as follows:

- 24. Upon information and belief,S pectralytics is a corporation organized and existing under the laws of the State of Minnesota, having a place of business at 145 South 3rd Street,

 Dassel, Minnesota-55325-0911.
- 25. Cordis is a corporation organized and existing under the laws of the State of Florida, having its principal places of business at 40 Technology Drive, Warren, New Jersey and at 1420 1 N.W.6 0th Avenue, Miami Lakes, Florida.

- 26. This counterclaim arises under the Declaratory JudgmentA cta nd the Patent Laws of the United States, more particularly under Title 28 U.S.C. §§ 2201 and 2202 and Title 35 U.S.C. §§ 100, et seq., respectively. This court has jurisdiction under Title 28 U.S.C. §§ 1338 and 2201.
- 27. An actual and justiciable controversy exists between Cordis and Spectralytics as to the infringement and validity of the '653 and '277 patents, as evidenced, inter alia, by the Complaint and Answer in this action.
- 28. On information and belief, U nited States Letters PatentN o. 6,114,653, entitled "Method of Cutting Hollow Workpieces with a Laser" and issued September 5, 2000, and United States Letters Patent No. 5,852,277, entitled "Laser Cutting Tool for Cutting Elongated Hollow Workpieces," and issued December 22, 1998, are invalid, void and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, sections 101,102, 103,and 112.
- 29. Cordis has not directly infringed any claim of the '653 patent or the '277 patent, either literally or under the doctrine of equivalents.
- 30. Cordis has not contributorily infringed or induced infringement of any claim of the '653 patent or the '277 patent.
- 31. On information and belief, S pectralytics is estopped from asserting that Cordis has infringed the claims of the '653 patent due to the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee in proceedings...... before the United States Patent and Trademark Office.
- 32. On information and belief,S pectralytics is estopped from asserting that Cordis has infringed the claims of the '277 patent due to the amendments of claims and arguments and

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other statements made during the prosecution by or on behalf of the patentee in proceedings before the United States Patent and Trademark Office.

33. Upon information and belief, S pectralytics is barred, in whole or in part, from recovery for the alleged infringement by Cordis by reason of Spectralytics' failure to comply with the requirements of 35 U.S.C. § 287.

WHEREFORE, Cordis prays for an adjudication against Spectralytics as follows:

- A. That Spectralytics' Complaint be dismissed with prejudice;
- B. That Spectralytics and all parties in active concert therewith be enjoined from asserting the '653 and '277 patents against Cordis;
 - C. That the claims of the '653 and '277 patents be declared invalid;
 - D. That the claims of the '653 and '277 patents be declared unenforceable;
 - E. That the claims of the '653 and '277 patents be declared not infringed by Cordis;
- F. That this case be declared exceptional under 35 U.S.C. § 285, and that Cordis be awarded its reasonable attorney fees and expenses of litigation againstS pectralytics;
 - G. That Cordis be awarded costs of this suit; and
- H. That Cordis be awarded such other and further relief as this Court shall deem just and proper.

6

JURY DEMAND

Counterclaim Plaintiff Cordis hereby respectfully requests trial by jury on all issues

triable to a jury.

Dated: December 21, 2005

ANTHONY OSTLUND & BAER, P.A.

By s/Joseph W. Anthony
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Courtland C. Merrill (#311984)
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William E. Craco JOHNSON & JOHNSON One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 (732) 524-3000

Attorneys for Defendant/Counterclaim Plaintiff Cordis Corporation

EXHIBIT 5

Case 0:05-cv-01464-PJS-RLE Document 1-1 Filed 07/21/2005 Page 1 of 4

IN THE UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

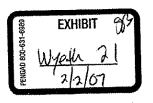
SPECTRALYTICS, INC.)
D1 1 400)
Plaintiff,	
	Civil Action No. 05 CV 1464
vs.) Judge:
) Magistrate Judge:
CORDIS CORPORATION) JET/FU
) JURY TRIAL DEMANDED
Defendant.)
)
)

COMPLAINT

This is a complaint for patent infringement arising under the patent laws of the United States. Plaintiff SPECTRAlytics, Inc., for its Complaint, states as follows:

THE PARTIES

- 1. Plaintiff SPECTRAlytics, Inc. ("SPECTRAlytics") is incorporated under the laws of Minnesota and has a principal place of business at 145 South 3rd Street, Dassel, Minnesota 55325-0911. SPECTRAlytics is engaged in, among other things, the business of making surgical stents.
- 2. Upon information and belief, Defendant Cordis Corporation ("Cordis") is incorporated under the laws of the state of Florida and has a principal place of business at 14201 N.W. 60th Avenue, Miami Lakes, Florida 33014. Upon information and belief, Defendant Cordis is engaged in the business of, among others, making and selling surgical stents.





JURISDICTION

- This is an action for patent infringement arising under the Acts of Congress 3. relating to patents, 35 U.S.C. §§ 271, 281-285.
 - This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). 4.

COUNT I INFRINGEMENT OF U.S. PATENT NO. 6,114,653

- Plaintiff SPECTRAlytics is the owner of United States Patent No. 6,114,653 ("the 5. '653 patent") entitled "Method of Cutting Hollow Workpieces with a Laser," which duly and legally issued on September 5, 2000.
- By its actions relating to the making and/or selling of surgical stents, Cordis is 6. liable as an infringer of the '653 patent under one or more of subsections (a) through (i) of 35 U.S.C. § 271.
- Plaintiff has suffered damages including irreparable harm due to Cordis' 7. infringement of the '653 patent and will continue to suffer irreparable harm in the future unless Cordis is enjoined from further infringement of the '653 patent.
 - Cordis has been aware of the '653 patent and its infringement is willful. 8.

COUNT II INFRINGEMENT OF U.S. PATENT NO. 5,852,277

- Plaintiff SPECTRAlytics is the owner of United States Patent No. 5,852,277 ("the 9. '277 patent") entitled "Laser Cutting Tool for Cutting Elongated Hollow Workpieces," which duly and legally issued on December 22, 1998.
- By its actions relating to the making and/or selling of surgical stents, Cordis is 10. liable as an infringer of the '277 patent under one or more of subsections (a) through (i) of 35 U.S.C. § 271.

Case 0:05-cv-01464-PJS-RLE Document 1-1 Filed 07/21/2005 Page 3 of 4

- 11. Plaintiff has suffered damages including irreparable harm due to Cordis' infringement of the '277 patent and will continue to suffer irreparable harm in the future unless Cordis is enjoined from further infringement of the '277 patent.
 - 12. Cordis has been aware of the '277 patent and its infringement is willful.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for the following relief:

- a. A judgment that Cordis has infringed U.S. Patent No. 6,114,653;
- b. A judgment that Cordis' infringement of U.S. Patent No. 6,114,653 is willful;
- c. A preliminary injunction enjoining and restraining Cordis, its officers, directors, agents, servants, employees, attorneys and all others acting under or through it, directly or indirectly, from infringing U.S. Patent No. 6,114,653;
- d. A permanent injunction enjoining and restraining Cordis, its officers, directors, agents, servants, employees, attorneys and all others acting under or through it, directly or indirectly, from infringing U.S. Patent No. 6,114,653;
 - e. A judgment that Cordis has infringed U.S. Patent No. 5,852,277;
 - f. A judgment that Cordis' infringement of U.S. Patent No. 5,852,277 is willful;
- g. A preliminary injunction enjoining and restraining Cordis, its officers, directors, agents, servants, employees, attorneys and all others acting under or through it, directly or indirectly, from infringing U.S. Patent No. 5,852,277;
- h. A permanent injunction enjoining and restraining Cordis, its officers, directors, agents, servants, employees, attorneys and all others acting under or through it, directly or indirectly, from infringing U.S. Patent No. 5,852,277;

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- i. A judgment and order requiring Cordis to pay all appropriate damages under 35 U.S.C. § 284, including treble damages if the infringement of the patents in suit is determined to be willful;
- j. A judgment and order requiring Cordis to pay the costs of this action, including all disbursements, and attorney fees if this case is exceptional as provided by 35 U.S.C. § 285, with prejudgment interest; and
 - k. Such other and further relief that this Court may deem just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues triable by jury.

SPECTRAlytics, Inc.

By its attorneys,

Dated: 1/21/05

Alan G. Carlson (MN #14,801)

Philip P. Caspers (MN #192,569)

Matthew J. Goggin (MN #210,705)

Dennis Bremer (MN #299,182)

Deakin T. Lauer (MN #321,515)

CARLSON CASPERS VANDENBURGH

& LINDQUIST, P.A.

225 South Sixth Street, Suite 3200

Minneapolis, Minnesota 55402

Phone: (612) 436-9600

Fax: (612) 436-9605

EXHIBIT 6

	D STATES DISTRICT COURT RN DISTRICT OF KENTUCKY AT LEXINGTON	Bestern District of Kentucky
		AUG 29 2005
CLAUDE CONRAD and	1	
BRENDA CONRAD)	AT LEXINGTON LESLIE G WHITMER CLERK U S DISTRICT COURT
PLAINTIFFS,) Civil Action No. :05CV-3	
v.)	
CORDIS CORPORATION)	
DEFENDANT.)	

Document 35

ANSWER OF DEFENDANT CORDIS CORPORATION

Defendant Cordis Corporation ("Cordis") for its Answer to Plaintiffs' Complaint, states as follows:

PARTIES AND SERVICE OF PROCESS

- 1. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraph 1 of Plaintiffs' Complaint, and therefore deny the same. To the extent that any of the allegations in Paragraph 1 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.
- 2. In response to Paragraph 2 of the Plaintiffs' Complaint, Cordis admits that it is a Florida corporation with its principal place of business in Florida. Cordis further admits that it designed, manufactured, marketed, distributed and sold the Cypher® Sirolimus-Eluting Coronary Stent ("Cypher® Stent") pursuant to the Premarket Approval granted by the Federal Food and Drug Administration ("FDA"), and that the Cypher® Stent is sold in the United States

and foreign jurisdictions. Lastly, Cordis admits that it can be served with process through the Kentucky Secretary of State. Cordis denies any allegation in Paragraph 2, not specifically admitted.

JURISDICTION AND VENUE

3. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraph 3 of Plaintiffs' Complaint, and therefore, Cordis denies these allegations.

FACTUAL BACKGROUND

- 4. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraphs 4 and 5 of Plaintiffs' Complaint, and therefore Cordis denies these allegations. To the extent that any of the allegations in Paragraphs 4 and 5 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.
- In response to Paragraph 6 of the Plaintiffs' Complaint, Cordis admits that the Cypher® Stent is a safe and effective treatment for certain cardiac conditions as determined by the patient's treating physician.
- In response to Paragraph 7 of the Plaintiffs' Complaint, Cordis admits that it 6. marketed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies any of the remaining allegations in Paragraph 7.
- 7. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraphs 8 through 13 of Plaintiffs' Complaint, and therefore, Cordis denies these allegations.

FRAUDULENT CONCEALMENT

- 8. Cordis denies the allegations in Paragraph 14 of Plaintiffs' Complaint.
- 9. In response to Paragraph 15 of the Plaintiffs' Complaint, Cordis admits that sometime in 2004, Plaintiff or representative of Plaintiff contacted Cordis to disclose complications allegedly related to the Cypher® Stent. Cordis denies the remaining allegations in Paragraph 15.
- 10. Cordis denies the allegations in Paragraph 16 of the Plaintiffs' Complaint. To the extent that any of the allegations in Paragraph 16 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.

CAUSES OF ACTION

NEGLIGENCE

- 11. In response to Paragraph 17 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 10 of its Answer.
- 12. The allegations in Paragraph 18 of the Plaintiffs' Complaint state a conclusion of law to which a response is not required. To the extent a response is required, Cordis states that it complied with all legal duties.
- The allegations in Paragraph 19 of the Plaintiffs' Complaint state a conclusion of law to which a response is not required. To the extent a response is required, Cordis states that it complied with all legal duties.
- Cordis denies the allegations in Paragraphs 20 through 26, including all subparts, of the Plaintiffs' Complaint. To the extent that any of the allegations in Paragraphs 20 through 26, including all subparts, allege or can be construed to allege that any product that may have

been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.

15. In response to Paragraph 27 of the Plaintiffs' Complaint, Cordis denies that Plaintiffs are entitled to recover against Cordis based on any legal theory, and Cordis specifically denies that Cordis caused any damages or injuries to Plaintiffs that would entitle Plaintiffs to any relief.

STRICT PRODUCTS LIABILITY (Defective Product)

- 16. In response to Paragraph 28 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 15 of its Answer.
- In response to Paragraph 29 of the Plaintiffs' Complaint, Cordis admits that it is the manufacturer of the Cypher® Stent and that it designs, markets and distributes the Cypher® Stent pursuant to the Premarket Approval granted by the FDA. Cordis denies all of the remaining allegations in Paragraph 29 of the Plaintiffs' Complaint.
- 18. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraphs 30 and 31 of Plaintiffs' Complaint, and therefore, Cordis denies these allegations.
- 19. Cordis denies the allegations stated in Paragraphs 32 and 33, including all subparts, of Plaintiffs' Complaint. To the extent that any of the allegations in Paragraphs 32 and 33, including all subparts, allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.
 - 20. Cordis denies the allegations in Paragraph 34 of the Plaintiffs' Complaint.

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21. Cordis denies the allegations in Paragraph 35 of the Plaintiffs' Complaint.

STRICT PRODUCTS LIABILITY (Defective Marketing and Inadequate Warning)

- 22. In response to Paragraph 36 of the Plaintiffs' Complaint, Cordis incorporates by reference the responses in Paragraphs 1 through 21 of its Answer.
- 23. In response to Paragraph 37 of the Plaintiffs' Complaint, Cordis admits that it is the manufacturer of the Cypher® Stent and it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 37 of the Plaintiffs' Complaint.
- 24. Cordis denies the allegations stated in Paragraphs 38 through 40 of Plaintiffs' Complaint. To the extent that any of the allegations in Paragraphs 38 through 40 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.
 - 25. Cordis denies the allegations in Paragraph 41 of the Plaintiffs' Complaint.

BREACH OF EXPRESS WARRANTY

- 26. In response to Paragraph 42 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 25 of its Answer.
- 27. In response to Paragraphs 43 through 46, including all subparts, of the Plaintiffs' Complaint, Cordis admits that it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraphs 43 through 46, including all subparts. To the extent that any of the allegations in Paragraphs 43 through 46, including all subparts, allege or can be construed to allege that any

product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.

28. Cordis denies the allegations in Paragraph 47 of the Plaintiffs' Complaint.

NEGLIGENT MISREPRESENTATION

- 29. In response to Paragraph 48 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 28 of its Answer.
- 30. In response to Paragraphs 49 and 50 of the Plaintiffs' Complaint, Cordis admits that it designed, manufactured, marketed, distributed and sold the Cypher® Stent pursuant to the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraphs 49 and 50. To the extent that any of the allegations in Paragraphs 49 and 50 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations.
 - Cordis denies the allegations in Paragraph 51 of the Plaintiffs' Complaint. 31.

- 32. In response to Paragraph 52 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 31 of its Answer.
- In response to Paragraph 53 of the Plaintiffs' Complaint, Cordis admits that it designed, manufactured, marketed, distributed and sold the Cypher® Stent pursuant to the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 53.

34. In response to Paragraphs 54 through 59 of the Plaintiffs' Complaint, Cordis denies these allegations and states that it did not disseminate any false, misleading or deceptive information regarding any of its products.

CONSUMER PROTECTION ACT

- 35. In response to Paragraph 60 of the Plaintiffs' Complaint, Cordis incorporates by reference, the responses in Paragraphs 1 through 34 of its Answer.
- 36. Cordis denies the allegations stated in Paragraphs 61 and 62 of Plaintiffs' Complaint. To the extent that any of the allegations in Paragraphs 61 and 62 allege or can be construed to allege that any product that may have been designed, manufactured, marketed, distributed or sold by Cordis was defective or unreasonably dangerous, Cordis specifically denies these allegations and states that it did not disseminate any false, misleading or deceptive information regarding any of its products.
 - 37. Cordis denies the allegations in Paragraph 63 of the Plaintiffs' Complaint.

GENERAL DAMAGES

- 38. Cordis denies the allegations in Paragraphs 64 and 65 of the Plaintiffs' Complaint.
- 39. Cordis denies each and every allegation in the Complaint that is not specifically admitted herein.

AFFIRMATIVE DEFENSES

Although Cordis has not yet had the opportunity to investigate or conduct discovery regarding Plaintiffs' Complaint, it believes there may be facts establishing the availability of certain affirmative defenses. In order to preserve those defenses, Cordis alleges the following:

FIRST AFFIRMATIVE DEFENSE

The claims asserted against Cordis are preempted either in whole or in part by the Federal Food, Drug & Cosmetic Act, the Medical Device Amendments thereto and/or any regulations promulgated thereunder, and the Supremacy Clause of Article VI of the United States Constitution and/or by the doctrine of deference to agency expertise.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim against Cordis upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Cordis affirmatively alleges that all claims asserted in the Plaintiffs' Complaint against it are barred either in whole or in part by the applicable statutes of limitations including K.R.S. §413.140.

FOURTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs rely on any theory of breach of warranty, any such claims are barred based upon Plaintiffs' lack of privity with Cordis and, additionally, because there was no reliance upon any warranties, if any, of Cordis.

FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs rely on any theory of breach of warranty, any such claims are barred in that Plaintiffs failed to provide Cordis with timely notice of any alleged breach of warranty. Cordis asserts each and every defense and presumption available under the Kentucky Uniform Commercial Code, codified in K.R.S. 355.2-101 et seq.

SIXTH AFFIRMATIVE DEFENSE

Cordis affirmatively alleges that the Plaintiffs had full knowledge of the risks and possible adverse consequences pertaining to the medical treatment received and all or part of the injuries, damages and/or losses sustained by Plaintiffs, if any, arose from, and were caused by, risks of which Plaintiffs were so aware, and such risks were accepted and assumed by Plaintiffs, and for that reason, any recovery against Cordis should be diminished, reduced, offset or barred, in accordance with the principles of informed consent.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained any of the injuries alleged in the Complaint, which Cordis denies, there was an intervening and/or superseding cause or causes leading to such alleged injuries and, as such, any action or omission on the part of Cordis was not a proximate cause of Plaintiffs' alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained any of the injuries alleged in the Complaint, which Cordis denies, said injuries were caused in full or in part by the conduct of one or more persons for whose conduct Cordis is not responsible or with whom Cordis has no legal relations. Cordis may therefore be entitled to contribution, indemnity and/or apportionment of fault.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained the injuries or incurred the expenses alleged in the Complaint, which Cordis denies, such injuries and/or expenses resulted from pre-existing and/or unrelated. medical, genetic and/or idiosyncratic conditions, diseases or illness of Plaintiffs.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against Cordis are barred because Cordis neither owed nor breached any duty to Plaintiffs.

ELEVENTH AFFIRMATIVE DEFENSE

Cordis states that any and all causes of action maintained by Plaintiffs against it based upon any alleged defect in its product are barred by the "learned intermediary" doctrine, or the "informed intermediary" doctrine, and/or the principles of §388 of the Restatement (Second) of Torts.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the methods, standards, and techniques utilized by Cordis in designing and manufacturing the product in question and in issuing warnings and instructions with respect to its use were in conformity with the generally recognized, reasonably available, and reliable state of knowledge in the field at the time the product was manufactured.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to name one or more necessary and indispensable parties.

FOURTEENTH AFFIRMATIVE DEFENSE

The Cypher® Stent is a prescription device designed, manufactured and distributed in accordance with its approval by the FDA as a safe and effective medical device as labeled, and is neither defective nor unreasonably dangerous because it falls within the Comment k exception to strict liability as outlined in the Restatement (Second) of Torts, Section 402(A).

FIFTEENTH AFFIRMATIVE DEFENSE

Cordis asserts each and every defense and presumption under Kentucky's Product Liability Act, K.R.S. 411.300 et seq.

SIXTEENTH AFFIRMATIVE DEFENSE

Cordis was not under any legal obligation to give the Plaintiffs notice or warnings about the use of Cypher® Stent. All notices or warnings were properly given to physicians, the only persons authorized by law to prescribe Cypher® Stent.

SEVENTEENTH AFFIRMATIVE DEFENSE

The conduct of Cordis and the Cypher® Stent conformed to the state of the art at all relevant times.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the equitable doctrines of laches, waiver, and estoppel.

NINETEENTH AFFIRMATIVE DEFENSE

Cordis reserves the right to assert other such defenses as may become available or appear during discovery proceedings in this case and hereby reserves the right to amend its answer to assert any such defenses.

WHEREFORE, Cordis respectfully requests that the Plaintiffs' Complaint be dismissed with prejudice at Plaintiffs' cost, that Cordis be awarded its costs and expenses, including reasonable attorneys' fees to the extent permitted by law, and for such further relief as this Court deems just and equitable.

Respectfully submitted,

Hammond by Knotial Warredt

Lori E. Hammond

FROST BROWN TODD LLC

400 W. Market St., 32nd Floor

Louisville, KY 40202

(502) 589-5400

Counsel for Cordis Corporation

CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing was served via first class mail on August 29, 2005 upon:

David L. Helmers DAVID L. HELMERS & ASSOCIATES, PLLC 163 East Main Street, Suite 300 Lexington, Kentucky 40507 (502) 252-2927 (telephone)

Melbourne Mills, Jr. LAW OFFICES OF MELBOURNE MILLS, JR., PLLC 163 East Main Street, Suite 100 Lexington, Kentucky 40507 (502) 873-8714 (telephone)

LOULibrary 486243v.1

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

f #	
DIE 19 23	FII 3:27
	CAMBRAM

Case No. 0 = -P3 571 (PAC)
LANCE CASSINO.

Plaintiff,

v.

JOHNSON & JOHNSON d/b/a CORDIS CORPORATION,

Defendants.

NOTICE OF REMOVAL

TO: LANCE CASSINO. AND HIS ATTORNEYS OF RECORD:

NOTICE IS HEREBY GIVEN that pursuant to 28 U.S.C. § 1441 Defendants JOHNSON & JOHNSON and CORDIS CORPORATION, hereby remove this action from the District Court, Arapahoe County, State of Colorado (Case No. 04 CV 1512), to the United States District Court of Colorado, based on the following:

1. Plaintiff Lance Cassino, has brought a civil suit against Defendants in the District Court, Arapahoe County, State of Colorado entitled Lance Cassino v. Johnson & Johnson d/b/a Cordis Corporation, Case No. 04 CV 1512. Copies of the Summons and Complaint are attached to this Notice as EXHIBIT A and constitute all processes, pleadings and orders served upon Defendants in this action to the present date. Pursuant to D.C.COLO.LCivR 81.1, Defendants submit (attached hereto as EXHIBIT B), copies of all state court pleadings, motions, and other papers as maintained for public access on the state court's web-based docket for this case.

- This Notice of Removal is filed within thirty (30) days after the service of process of Plaintiff's Complaint. The first date upon which Defendants received the Complaint was February 24, 2005.
- 3. The above-described matter is a civil action over which this Court has original "diversity" jurisdiction pursuant to 28 U.S.C. §1332 and is removable under 28 U.S.C. §1441 et seq., in that the matter in controversy is a civil action between citizens of different states in which the amount in controversy exceeds \$75,000 exclusive of interest and costs.
- 4. Plaintiff is a citizen of Colorado (see Complaint ¶ 1); and Defendants are neither incorporated in nor have their principal place of business in Colorado. Defendant Johnson & Johnson is incorporated and has its principal place of business in New Jersey. Defendant Cordis Corporation is incorporated and has its principal place of business in Florida.
- The underlying facts alleged in this action support an amount in controversy well in excess of the court's jurisdictional limit of \$75,000. The Complaint alleges a cause of action for strict liability, negligence, breach of implied warranty of merchantability, and seeks personal injury damages allegedly caused by Plaintiff's use of heart stents allegedly manufactured by Defendants. The alleged damages include "past and future non-economic and physical impairment and disfigurement injuries, damages and losses, including impairment of quality of life; inconvenience; pain and suffering; emotional distress and losses of consortium." (Complaint, ¶14, 18, 23). The alleged damages also include economic losses for past and future doctors' bills, bills for medications, and expenses for therapeutic treatment. (Complaint, ¶14, 18, 23). Additionally, Plaintiff alleges "sustained past and future economic losses, including

loss of home services, and loss of income for Mr. Cassino." (Complaint, ¶14, 18, 23). Plaintiff also claims damages for loss of employment sponsored health insurance and his consequential inability "to qualify for private health insurance plans" which has "rendered him without healthcare since 2002." (Complaint, ¶14). Finally, Plaintiff asserts a claim for "Exemplary/Punitive Damages." (Complaint, "Fourth Claim For Relief," ¶24-26.) In pre-filing litigation, Plaintiff's counsel has valued the case at over \$676,000 with economic losses exceeding \$426,000 and non-economic losses exceeding \$250,000; well in excess of the court's \$75,000 jurisdictional threshold. See July 1, 2004 letter from Plaintiff's counsel to Defendant Johnson & Johnson attached hereto as EXHIBIT C.

- 6. Written notice of the filing of this Notice of Removal and a copy of the Notice of Removal were served upon Plaintiff's attorney of record, by first class mail, on this 28th day of March, 2005, and will be filed no later than the close of business on March 28th, 2005, in the District Court, Arapahoe County, State of Colorado, pursuant to 28 U.S.C. § 1446(d).
- 7. Defendants are not any waiving jurisdictional challenges or defenses by removing this action to Federal Court and expressly reserve their right to assert such challenges and defenses at the appropriate time.

WHEREFORE, Defendants respectfully pray that the above action now pending against them in the District Court, Arapahoe County, State of Colorado be removed to the United States District Court for the District of Colorado.

Respectfully submitted this 28th day of March, 2005.

SOCHA PERCZAK SETTER & ANDERSON, P.C.

Griffith A. Kundahl

Denver Financial Center, Tower I 1775 Sherman Street, Suite 1925

Denver, CO 80203 Phone: (303) 832-7265 Fax: (303) 832-7438

ATTORNEYS FOR DEFENDANTS
JOHNSON & JOHNSON and CORDIS CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of March, 2005, a true and correct copy of the foregoing NOTICE OF REMOVAL was placed in the United States mail, postage pre-paid, properly addressed to:

Clerk of Court Arapahoe County District Court 7325 South Potomac Street Centennial, CO 80112

Carol J. Zeisler, Esq. William Muhr, Esq. 7035 Campus Drive Colorado Springs, CO 80920

Patricia Cranney

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ARAPANDE COUNTY DISTRICT COURT, Court Address: 7325 S. Potomiac Centennial, Colorado ED112 CABSING, LANCE, Plainuns, A MOZNÁCL JOHNSON JONE CORDIS CORPORATION ? COURT USE ORLY? Defendants. Attorneys; Case Number. Carol J. Zeister, #035091 Name: Division: William Muhr, #018093 Address: 7035 Campus Drive Countroom; Colorado Springs, CO 80920 (719) 598-9577 Telephone: (719) 598 3932 Facsimile: e-mail: muhri Docisyanet COMPLAINT

COME NOW the Plaintif, Lance Cassino, by and through his attornays, William Mulin, Attorneys & Counsations at Law, LLP, and for his claims for rolled against the detendent Johnson & Johnson dibital Comits Corporation (hereinafter Johnson), allege as follows:

JURISDICTION AND VENUE

1. The Plaintill, Lance Cassino, was and is a resident of the City of Conflex.

County of Jefferson, and State of Colorado at the time of the May 30, 2002 myocardial

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infaction and at at 67,22 relevant to this Complaint. Mr. Cassine accepts the jurisdiction of Alapabae County for this cause of action.

- Defendant, Clordis Corporation, is a corporation organized and existing under the laws of the State of Florida and has its principal place of husiness located at 14201 N. W. 60° Avonue, Miami Lakes, Plorida 33074. Defendant, Corolis Corporation is a subsidiery of Johnson & Johnson. Johnson & Johnson is a corporation organized and crising under the laws of the State of Now Jersey and has its principal place of business tecated at One Johnson & Johnson Plaza, New Brunswick, New Jersey (16938. Johnson & Johnson is responsible for all of Consis Corporation's operations, including the marjutacture of the JJIS and Palmaz-Schatz intracomery sterit
- Distanciant, Johnson, is responsible for the research, design and development of all LES and Palmaz-Schalz intracommery stents.
- 4. Venue is proper in that the injuries complained of occurred in the County of Arspahoc, City of Enginwood, and State of Colorado.
- 5. Colorado larri copilles to this matter in that the injuries occurred in Colorado and emérgency medical care was provided and subsequent medical treatments were provided in Coloredo.
- Colorad: baw is also to be applied under the significant contacts analysis as S. prescribed by Internal 2018 Shoe Co. v. Washington, 326 US 310 (1945). For the specific purpose of the international Shop analysis the signatural contacts, applicable here, are as follows: 1) Plaintiff, at all times relevant to this scrion, was dominited in Colorado: 2) Substantial medical trustments was incurred by Philatill, Lance Cassino, in Englewood, Co sinde March 20, 2000 for the Injuries sustained in caused by the stants; 2) All of Mr.

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Cashino's reasonable and necessary medical care and treatment was provided by Confindo licemand physicians; 4) the stems herein at lesue were purchased in Colorado; 5) the sixual complained of herein remain in Colorado; Plainell continue to reside in Colorado et P.O. Box 4050, Coniter, CO 80423; and the willnesses and non-retrieve experts such as aparaing physicians are currently residents of Colorado.

GENERAL ALLEGATIONS

- The sile; zitions contained in oxing reports 1 through 8 are reported and realleged as if fully set forth heroin.
- On December 1, 1996, Plaintiff, Lance Cassino, went to Columbia Swedish Medical Center at 501 East Hampdon Avanue, Englewood, Colorado 90110, because he was experiencing chest bein. On December 3, 1895, Mr. Cassino underwom cardiac extremendation by Dr. Ira Kowal because of unstable angina. Coronary Intervention was warfanted and Dr. David Gonzalez performed the procedure. Dr. Gonzalez pieced four (4) JUS Palmaz-Schatz intracoronory attents into Mr. Cassino's arteries in order to allow the blood to flow freely, (E utribl! A).
- On March 30, 2002, Mr. Cassino returned to Columbia Swedish Modical Confer a second time, again for chest pain. At this time he was diagnosed with a second mydicardial interction despite being eulipidemic. He was hospitalized in the intensive Care Unit for three days and released with medications. It has since been discovered that sterils are not effective against the primary cause of myocordial infarction, inflammation. In fact, they imitate the living of the coronary anteries increasing the patient's propensity for both myocardial informion due to stein local effect and corebnal unscaller accidents (strikes) due to the chronic inflammatory effect the have systemically. The newer stems,

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coased with medications designed to prevent inflammatory reaction may improve the outcome for stented pullients but the mojerity of condictory literature published today offers lowering choisternal and connecting dysopiciemias as the most critical tactions in preventing myocoardial inflammans. Wr. Cassino had already corrected these factors between 1996 and 2002 and thus but for the implammed stents ha was not at increased list of recodurence.

10. Defendant did not properly inform the public and/or medical community of the passible risks associated with the stents. If Mr. Cassine had been properly informed of the insits regarding implantation of the LLS Palmax-Scholz increoronary stents and possible atternatives his would not have consented to the implantation of the stents and within a reasonable mudical probability, not had the 2002, second, myocardial intention.

FIRST CLAIM FOR PEUEF (Negligence agains! Detendard Johnson)

- 11. The alle jations contained in paragraphs 1 through 10 are repeated and realleged as if fully set to the rein.
- i 12. Upon information and ballet, said Defendent designed and manufactured the Julis Palmaz-Schutz in recordingly stends and its negligent design and manufacture caused the Plaintin to suiter an other myocardial infanction and thereby cause the Plaintin's Injuries, darriages and losses it entitled more fully above.
- 13. Defends it Johnson was negligent including but not limited to the following including but not limited to the following
 - a. Ely designing, manufacturing, and selling an unreasonably

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an igenous intracoronary stant, in that the product had a proctivity to cause scar besue thereby increasing the risks of further myocardial informations;

- By fasting to improve the costion, to retrofit the product, to recall or otherwise to notify the Plaintiff of the product defect or otherwise to remedy the defect prior to May 30, 2002;
- By falling to instruct in the proper selection of patients for the product?
- B; falling to warn of the defects in the design of the intracoronary stort.
- By follog to warn adequately the public and the Pleinfill or the extreme and unreasonable hazards and dangers of the intraporonary stent; and/or
- B; withholding from the public and specifically the Flaintil information concerning the defects and/or possible risks of the intracoromacy stant, its intrapts, and the fact that the product has a safety-related defect.
- 1.1. As a direct and proximate result of the negligence of Defendant, as alteged trorbin, the Plaintiff has sustained the aforementioned past and future non-economic and physical impairment and disfigurement injeries, damages and losses, including impairment of this quality of life; inconvenience; poin and suffering; emotional distress and losses of confectium. As a further direct and proximate result of Defendant's conduct as aforesaid. Plaintiff, Lance Cassino, has incurred doctors' bills hospital bits, bills for medications, and expenses for therapeutic treatment and will in the future incur such bits, costs and expenses over his literane. Further, Plaintiff has sustained past and future economic losses, including loss of home services, and loss of income for the Cassino. Finally, Mr. Cassino, due to his loss of employment has suffered the loss of his employer-sponsored health insurance and is he is unable to qualify for private health insurance plans this has rendered than without heatingers since 2002.

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SECOND CLARKFOR RELIEF (Strict Liebility Defendent Johnson)

- 15. The allegations contained in paragraphs 1 through 14 are repected and re allegad as it turns sections recein.
- 16. At the time of the design, manufacture, and sale of the Pelmas-Schatz stent. Johnson knowingly and with reckless disregard, withheld critical information regarding the occurrence of inflammation and plateiet aggregation at the site of implantation at the Pa. next-Schatz stem efter research from multiple sites had revealed this phenomena. The inflect of this failure to disclose critical research and aneccotal reports was that physicians and patterns were deprived of this information when making surgical decisions.
- 17. The Defindants taiture to adequately design and to warn adequately of the product or to recoil the product once the Defendant learned of the defective nature of the Palmax-Schatz stont rendered the product unreasonably dangerous to its users, including the Plaintiff, Lence Cassino.
- 18. As a result of the defects and failures destribed above, said Defendent is study liable to the Philintiff, Lance Cassino, who sustained permanent injuries as a result of the defective and Limeaschably denganous condition of the product. Mr. Cassino has required the services of physicians, hospitalization for intensive care. Plaintiff, Lance Cassino, suffered all the aforementioned injuries damages and losses. Furthermore, as a direct and proximate result of the Defendent's negligence, Plaintiff has an impairment of the quality of his life; inconvenience; pain and suffering; emotional diamess and other peak and future non-economic damages. As a further direct and proximate result of Defendent's conduct to aforesaid, Plaintiff, Mr. Cassino, also has incurred decions' bills.

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hospital bills, bills for medications, and expenses for therapeutic treatment and will, in the future, incur such bills, costs and expenses over his lifetime. Further, Plantiff has suspined part and future economic losses, including loss of home pervices as well as loss of leasure.

THIRD CLAIM FOR RELIEF

(Breach or implied Warranty of Merchantability against Defendant)

- 19. The allegations contained in paragraphs 1 prough 18 are repeated and realleged as if fully set forth herein.
- : 20. Defendant is a menchant with respect to goods of the kind involved in this action; i.e., Palmax-Schatz morzopronery stems.
- 21. The Describent impliedly warranted that the stents that it designed, marketizationed, and sold was merchantable.
- 22. The Detendent breached the implied warranty of merchantability because the blent was not fit for the ordinary purposes for which such goods are used, in that the product had a prodivity to cause scar history that blocked the artery when put to the use intended and the Detendent did not provide warrange about the dangers associated with the use of the product.
- 23. The Preintial sustained permanent injuries because of the Defendant's breach of the implied warranty of merchantability. The Plaintiff has required the services of physiosis, reconsisting hospitalization for intensive care, surgery, and the correction of internal injuries. Plaintiff, Lance Caesino suffers daily with the possibility or future, possibily fatal, heart salects from the placement of these stents. Furthermore, at a tired and proximate result of the Defendant's negligence, Plaintiff has an impairment of the quality of life; inconvenience; pain and suffering; emotional dishess and other past and

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future non-economic carriagos. As a further direct and proximate result of Defendants conduct. Plaintiff has incurred doctors' bills, hospital bills, bills for medications, and expenses for therapeutic treatment and will in the luture incur such bills, costs and excenses over his litaline. Further, Plantiffs have sustained past and future aconomic looses, including loss of nome services, loss of income and impairment to his earning copacity.

FORWING CLAIM FOR RELIEF (ExemplaryPunitive Damagos - Defendant Joimson)

- The Plaintiffs incorporate by reterence the foregoing paragraphs 1 through . 24. 23 as & fully expresser harein.
- The acts and priissions of Datendani were willful and wanton and performed in makless disregard for the rights and safety of others. Here, such egregious acts and omissions apply with particularity to Mr. Cassino because the Defendant knew, had reason to know, and should have known of the risks motion hazards inherent in the Palmaz-Schalz intracoronary signts. Additionally, in rackless and willful and winton disregard of the rights and safety of the consuming public, and perficularly to this Flaintiff, Defendant confinued to manufacture, self, and promote the Palmez-Schatz intracurrency stents without recoiling the defective product or without warning the public, including the Plaintiff, of the defective and dangerous nature of the stent
- 26. For the easons outlined above, the Defendant conduct entities the Plaintiff to recover exemplary damages to punish Defendant for past conduct and to defer the Defendant and others from similar egregious conduct in the future.

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Plaints furner prays that judgment by antered and that followers them countries are proper with the countries of proper and proper and proper and proper and proper and proper as proved together with pre-judgment interest from the date of Plaintiffs injuries as described and alleged above; post-judgment interest as allowed by law, exemplary damages; and such other relief as the Court deems proper. Plaints furner prays that judgment by antered and that the Court will award them costs, expert without less and compensation for loss of enjoyment of life.

Respectfully submitted this 29th day of March, 2004.

Wilkern Maur. Anomoles & Counsalors of Law, LLP

In Carol J. Zeisler
Carol J. Zeisler, #035(8)1

Addring of Phintitis Used Cytaked P.O., No. 1000 Contin, GO 6003

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

Case No.	<u> </u>	<u> </u>				[Times	رشاكة	^	<i>a</i> 5
LANCE CASSINO,		(deim.	KB	ess.	J.	6		(DAC)

Plaintiff,

V.

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JOHNSON & JOHNSON d/b/a CORDIS CORPORATION,

Defendants.

DEFENDANT CORDIS CORPORATION'S ANSWER, AFFIRMATIVE DEFENSES AND JURY DEMAND

COMES NOW Defendant Cordis Corporation, through its attorneys, Socha, Perczak, Setter & Anderson, P.C., and responds to Plaintiff's Complaint as follows:

JURISDICTION AND VENUE

- 1. Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 1 of the Complaint.
- 2. Cordis Corporation admits the allegations contained in the first sentence of paragraph 2 of the Complaint. Cordis Corporation denies the allegations contained in the second sentence of paragraph 2 of the Complaint as stated but admits that Cordis Corporation is a related entity of Cordis Corporation. Cordis Corporation admits the allegations contained in the third sentence of paragraph 2 of the Complaint. Cordis Corporation denies the allegations contained in the fourth and last sentence of paragraph 2 of the Complaint.

- 4. Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 4 of the Complaint. Cordis Corporation further states that the allegations contained in paragraph 4 of the Complaint constitute legal conclusions to which no response is required. To the extent this paragraph is deemed to require a response. Cordis Corporation states that it does not know.
- 5. Cordis Corporation states that the allegations contained in paragraph 5 of the Complaint constitute legal conclusions to which no response is required. Further, Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 5 of the Complaint.
- 6. Cordis Corporation states that the allegations contained in paragraph 6 of the Complaint constitute legal conclusions to which no response is required. Further, Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 6 of the Complaint.

GENERAL ALLEGATIONS

- 7. Cordis Corporation realleges and incorporates by reference its responses to each and every allegation contained in paragraphs 1 through 6 as if fully set forth here.
- 8. Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 8 of the Complaint.

- 9. Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first three sentences of paragraph 9 of the Complaint. Cordis Corporation denies the remainder of the allegations contained in paragraph 9 of the Complaint.
 - 10. Cordis Corporation denies the allegations of paragraph 10 of the Complaint.

FIRST CLAIM FOR RELIEF (Negligence)

- 11. Cordis Corporation realleges and incorporates by reference its responses to each and every allegation contained in paragraphs I through 10 as if fully set forth here.
- 12. Cordis Corporation lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first three sentences of paragraph 12 of the Complaint and therefore denies them. Cordis Corporation avers that it has satisfied all applicable legal duties of care.
- 13. Cordis Corporation denies the allegations of paragraph 13 of the Complaint. Cordis Corporation avers that it has satisfied all applicable legal duties of care and denies any wrongdoing whatsoever.
- 14. Cordis Corporation denies the allegations of paragraph 14 of the Complaint.
 Cordis Corporation avers that it has satisfied all applicable legal duties of care and denies any wrongdoing whatsoever.

SECOND CLAIM FOR RELIEF (Strict Liability)

15. Cordis Corporation realleges and incorporates by reference its responses to each and every allegation contained in paragraphs 1 through 14 as if fully set forth here.

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- 16. Cordis Corporation denies the allegations of paragraph 16 of the Complaint.
- 17. Cordis Corporation denies the allegations of paragraph 17 of the Complaint.
- 18. Cordis Corporation denies the allegations of paragraph 18 of the Complaint.

THIRD CLAIM FOR RELIEF (Breach of Implied Warranty of Merchantability)

- 19. Cordis Corporation realleges and incorporates by reference its responses to each and every allegation contained in paragraphs 1 through 18 as if fully set forth here.
- 20. Cordis Corporation states that the allegations contained in paragraph 20 of the Complaint constitute legal conclusions to which no response is required.
- 21. Cordis Corporation states that the allegations contained in paragraph 21 of the Complaint constitute legal conclusions to which no response is required. Cordis Corporation denies that it breached any warranties which might be implied by law; states that the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint were distributed with FDA-approved product label; states that it is without sufficient information to form a belief as to facts concerning Plaintiff and any notice that was given and, therefore, denies the same.
- 22. Cordis Corporation states that the allegations contained in paragraph 22 of the Complaint constitute legal conclusions to which no response is required. To the extent this paragraph is deemed to require a response, Cordis Corporation denies the averments contained therein. Cordis Corporation avers that it has satisfied all applicable legal duties of care and denies any wrongdoing whatsoever.
- 23. Cordis Corporation denies the allegations of paragraph 23 of the Complaint.

 Cordis Corporation avers that it has satisfied all applicable legal duties of care and denies any wrongdoing whatsoever. Cordis Corporation denies that it breached any warranties which might

be implied by law; states that the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint were distributed with FDA-approved product label; states that it is without sufficient information to form a belief as to facts concerning Plaintiff and any notice that was given and, therefore, denies the same.

FOURTH CLAIM FOR RELIEF (Exemplary/Punitive Damages)

- 24. Cordis Corporation realleges and incorporates by reference its responses to each and every allegation contained in paragraphs 1 through 23 as if fully set forth here.
 - 25. Cordis Corporation denies the allegations of paragraph 25 of the Complaint.
 - 26. Cordis Corporation denies the allegations of paragraph 26 of the Complaint.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Cordis Corporation in this matter. Cordis Corporation therefore asserts the following affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Cordis Corporation may withdraw any of these affirmative defenses as may be appropriate.

FIRST AFFIRMATIVE DEFENSE

Plaintiff fails to state facts sufficient to constitute a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the applicable statute of limitations.

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THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims, if any, are barred, in whole or in part, by the doctrines of laches, waiver, unclean hands, estoppel and/or ratification.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a); therefore, Plaintiff's causes of action fail to state a claim upon which relief can be granted in that such claims for relief, if granted, would impede, impair, frustrate or burden the effectiveness of federal law regulating the field of medical devices and would violate the supremacy clause (Article VI, Section 2) of the United States Constitution.

The Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint stents fall under the auspices of the Food, Drug and Cosmetic Act and regulations promulgated by the Food and Drug Administration and, therefore, Plaintiff's claims are preempted under the Supremacy Clause of the U.S. Constitution. Alternatively, Cordis Corporation is entitled to a presumption that the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint are not defective or unreasonably dangerous and that its labeling is adequate pursuant to C.R.S. § 13-21-403(1)(b).

FIFTH AFFIRMATIVE DEFENSE

Cordis Corporation alleges the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint are safe when used as directed, and Cordis Corporation reasonably assumed that its directions and warnings would be read and heeded.

SIXTH AFFIRMATIVE DEFENSE

Cordis Corporation alleges that the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint conformed to the state-of-the-art for the design, manufacture and warnings

of such or similar products. Cordis Corporation's actions and the stents conformed to the state of the art of reasonably available scientific and technological knowledge at all times relevant to this lawsuit. C.R.S. §13-21-403(1)(b).

SEVENTH AFFIRMATIVE DEFENSE

Cordis Corporation alleges that it made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff herein. If any such warranties were made, whether express or implied, which Cordis Corporation specifically denies, then Plaintiff failed to give timely notice of any breach thereof.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's injuries, losses and damages, if any, were due to an allergic, idiosyncratic or idiopathic reaction to the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint, or by an unforeseeable illness, unavoidable accident, or pre-existing condition, and not any negligent or culpable conduct by Cordis Corporation.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's damages, if any, were the result of Plaintiff's preexisting conditions or were not proximately caused by any act or omission of Cordis Corporation.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's action is barred because the Palmaz-Schatz intracoronary stents referred to in Plaintiff's Complaint are products that are unavoidably unsafe pursuant to the provisions of Section 402A of the Restatement (Second) of Torts, Comments k and j, and Colorado law upholding and applying these provisions, as well as the provisions of Section 4 et seq. of the Restatement (Third) of Torts.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims may be barred because Plaintiff assumed the risks associated with the use of the product or products referred to in his Complaint; and his claims may be barred under the principles of informed consent.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff was careless and negligent in the matters alleged, thereby causing and contributing to any injury, damage or loss to Plaintiff. Cordis Corporation requests that any finding of liability or judgment reflect the apportionment of fault attributable to Plaintiff.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the principles of the Learned Intermediary doctrine. Under the Learned Intermediary doctrine, Cordis Corporation only has a duty to warn the prescribing physician; as a result. Plaintiff's claims are barred by the Learned Intermediary doctrine.

FOURTEENTH AFFIRMATIVE DEFENSE

Cordis Corporation alleges that the Plaintiff's claims for punitive damages are in contravention of Cordis Corporation's rights under each of the following constitutional provisions:

- the Commerce Clause of Article I, Section 8 of the United States Constitution;
- the Contracts Clause of Article I, Section 10 of the United States b. Constitution;
- the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution;
 - the Supremacy Clause of Article IV of the United States Constitution; d.

(j)

- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution:
- h. the Right to Counsel of the Sixth Amendment of the United States Constitution:
- i. the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;
- j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;
- k. the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and
 - 1. any similar provisions under the Constitution of the State of Colorado.

FIFTEENTH AFFIRMATIVE DEFENSE

Because of the lack of clear standards, the imposition of punitive damages against Cordis Corporation is unconstitutionally vague and/or overbroad.

SIXTEENTH AFFIRMATIVE DEFENSE

No act or omission of Cordis Corporation was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's demand for exemplary damages is governed by those standards or limitations regarding the determination and enforceability of exemplary damages awards which arise under the United States Constitution, the decisions of the United States Supreme Court, including

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BMW of North America v. Gore, 116 U.S. 1589 (1996), its progeny and applicable and the applicable constitutional provisions, statutes and laws of the State of Colorado.

EIGHTEENTH AFFIRMATIVE DEFENSE

Cordis Corporation alleges that any claim for punitive damages based solely on a cause of action for strict liability is barred by Colorado law.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims, if any, are barred, reduced and/or limited pursuant to any other applicable limitations of awards, caps on recovery, and setoffs permitted by law, including but not limited to, C.R.S. §13-21-102.5 for noneconomic loss or injury, and C.R.S. §13-21-111.6 for amounts paid or provided by collateral sources.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff failed to exercise reasonable care and diligence to mitigate his alleged damages.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Cordis Corporation alleges that any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already or will in the future have, with reasonable certainty, indemnified Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff has failed to join all necessary and indispensable parties and therefore, complete relief cannot be accorded to those who are already parties to this action and Plaintiff's failure to join all indispensable parties will result in prejudice.

(1)

Cordis Corporation reserves the right to interpose further defenses to which it may be entitled as revealed by further proceedings.

WHEREFORE, Cordis Corporation prays for judgment as follows:

- 1. That Plaintiff take nothing by reason of his Complaint on file herein;
- 2. That the Court enter a judgment dismissing the Complaint against Cordis Corporation with prejudice;
- 3. That the Court award Cordis Corporation its reasonable expenses and costs, including but not limited to reasonable attorneys' fees, incurred in the defense of the Complaint; and
- 4. That the Court grant Cordis Corporation such other and further relief as the Court may deem proper.

DEFENDANT CORDIS CORPORATION DEMANDS A TRIAL TO A JURY.

Dated: March 28th, 2005

Respectfully submitted,

SOCHA PERCZAK SETTER & ANDERSON, P.C.

Griffith A. Kundahl

Denver Financial Center, Tower 1 1775 Sherman Street, Suite 1925

Denver, CO 80203 Tel: (303) 832-7265 Fax: (303) 832-7438

Attorneys for Defendant Cordis Corporation

Address of Defendant:

Cordis Corporation c/o Socha, Perczak, Setter & Anderson, P.C. Denver Financial Center, Tower I 1775 Sherman Street, Suite 1925 Denver, CO 80203

CERTIFICATE OF MAILING

I hereby certify that on this 28th day of March, 2005, a true and correct copy of the foregoing DEFENDANT CORDIS CORPORATION'S ANSWER, AFFIRMATIVE DEFENSES AND JURY DEMAND was placed, postage prepaid, in the U.S. Mail addressed to the following:

Carol J. Zeisler, Esq. William Muhr, Esq. 7035 Campus Drive Colorado Springs, CO 80920

Patricia Cranney

EXHIBIT 8

CHI

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

DEC 2004

AFTER HOURS DE POSITORY
Robot R. Di Trolio, Clerk
U.S. DIST COURT
W. D. OF TN. MEMPHIS

JACKIE L. McCONNELL

PLAINTIFF

VS.

No. 04 2989 DV

CORDIS CORPORATION, a JOHNSON & JOHNSON COMPANY; SURMODICS, INC.; and WYETH PHARMACEUTICALS, A Division of WYETH, INC.

DEFENDANTS

TO: THE JUDGES OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE, WESTERN DIVISION

Berry Cooper (No. 13196) Deal, Cooper & Holton, PLLC 296 Washington Avenue Memphis, TN 38103

ATTORNEYS FOR PLAINTIFF

Honorable Jimmy Moore 140 Adams Room 324 Memphis, TN 38103

SHELBY COUNTY CIRCUIT COURT CLERK

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1332, 1441 and 1446(b), Defendant Cordis Corporation ("Cordis"), a Florida corporation, expressly subject to all its Rule 12 and other defenses, hereby removes this case from the Circuit Court of Shelby County, Tennessee, to the United States District Court for the Western District of Tennessee, Western Division. As grounds for this removal, Cordis states the following:



- 1. This Action was commenced on or about November 4, 2004, by the filing of a Complaint in the Circuit Court of Shelby County, Tennessee, which bears Civil Action No. CT-006360-04. Attached hereto as Exhibit "A" is a copy of the court file from the Circuit Court of Shelby County, Tennessee, which, pursuant to 28 U.S.C. § 1446(a), includes copies of all process, pleadings and orders (if any) served on Cordis in this action.
- 2. Cordis hereby adopts and incorporates by reference its Answer and Affirmative Defenses being served concomitantly herewith, attached hereto as Exhibit "B." By filing this Notice of Removal, Cordis does not waive any right to assert any defense available to it under Tennessee and Federal Rules of Civil Procedure 12(b).
- 3. The Summons and/or Petition were served upon Cordis on November 9, 2004. Surmodics, the first served defendant, was served on November 8, 2004.
- 4. Because this Notice of Removal is filed within thirty days of service of the Summons and/or Complaint upon Surmodics, the first served defendant, it is timely under 28 U.S.C. §1446(b).
- 5. Surmodics, Inc., and Wyeth consent to removal of this case to federal court. See Exhibit "C."
- 6. This Action is one of a civil nature, wherein the United States District Court for the Western District of Tennessee, Western Division, has jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441 and 1446(b).
- 7. Pursuant to 28 U.S.C. § 1446(d), all adverse parties are being provided with written notice of removal, and a copy of this Notice of Removal is being filed with the Clerk of the Circuit Court of Shelby County, Tennessee.

I. Diversity Jurisdiction

- 8. According to Plaintiff's Complaint, Plaintiff is an adult resident citizen of the State of Tennessee. Cmpl. at ¶ 2.
- 9. At the time the Complaint was filed, at the time of removal, and during all intervening times, Cordis was (and is) a corporation organized under the laws of the State of Florida, with its principal place of business in the State of Florida. Cordis is, therefore, a "citizen" of the State of Florida. See 28 U.S.C. § 1332(c)(1)(deeming corporation to be a citizen of the State where it is incorporated and of the State where it has its principal place of business).
- 10. At the time the Complaint was filed, at the time of removal, and during all intervening times, Wyeth was (and is) a corporation organized under the laws of Delaware with its principal place of business in New Jersey. Wyeth Pharmaceuticals Division of Wyeth, incorrectly named in the Complaint as "Wyeth Pharmaceuticals, a division of Wyeth, Inc." is not a separate corporation but has its principal offices in Pennsylvania. Wyeth, therefore, is not and was not at the time of filing, a citizen of the State of Tennessee.
- 11. At the time the Complaint was filed, at the time of removal, and during all intervening times, Defendant Surmodics, Inc. was (and is) a corporation organized under the laws of Minnesota with its principal place of business in Minnesota. Surmodics, Inc., therefore, is not and was not at the time of filing, a citizen of the State of Tennessee.
- 12. This action is, therefore, an action "between citizens of different States" within the meaning of 28 U.S.C. section 1332(a)(1).
- 13. The amount in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000. *Cmpl.* at p. 20.

14. This Action, therefore, is a "civil action brought in a State court of which the district courts of the United States have original jurisdiction" within the meaning of 28 U.S.C. section 1441(a), and is properly removable to this Court.

WHEREFORE, PREMISES CONSIDERED, Cordis Corporation files this Notice of Removal and removes this civil action to the United States District Court for the Western District of Tennessee, Western Division. Plaintiff is hereby notified to proceed no further in state court.

DATED this the _____ day of December, 2004.

Respectfully submitted,

CHARLES C. HARRELL (#5886)

ATTORNEY FOR CORDIS CORPORATION

OF COUNSEL:

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC P.O. Box 171443 Memphis, Tennessee 38187-1443 Ph: (901) 680-7327

Fax: (901) 680-7201

CERTIFICATE OF SERVICE

I, Charles C. Harrell, one of the attorneys for Cordis Corporation, do hereby certify that I have this day served a true and correct copy of the above and foregoing Notice of Removal by mailing same via United States Mail, postage fully prepaid thereon, to the following:

Berry Cooper (No. 13196) Deal, Cooper & Holton, PLLC 296 Washington Avenue Memphis, TN 38103 ATTORNEY FOR PLAINTIFF

Honorable Jimmy Moore 140 Adams Room 324 Memphis, TN 38103 SHELBY COUNTY CIRCUIT COURT CLERK

James M. Doran, Jr. Waller Lansden Dortch & Davis, PLLC Nashville City Center 511 Union Street, Suite 2700 Nashville, TN 37219 ATTORNEY FOR SURMODICS

Samuel Felker Bass, Berry & Sims 315 Deaderick Street AmSouth Center Suite #2700 Nashville, Tennessee 37238-3001

Timothy Johnson Bass, Berry & Sims The Tower at Peabody Place 100 Peabody Place, Suite 900 : Memphis, TN 38103-3672 ATTORNEYS FOR WYETH

So certified, this the **3** d day of December. 2004.

- 5 -

CHARLES C. HARRELL

JACKSON 985005v1

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

N DIVIBEON 3 2PU4

JACKIE L. McCONNELL

AFTER HOURS DEPOSITORY
Rober RV DI Trolio, Clerk
U/S/DIST COURT
W. B. OF TN, MEMFHIS

VS.

No. 04 2989 0V

CORDIS CORPORATION, a JOHNSON & JOHNSON COMPANY; SURMODICS, INC.; and WYETH PHARMACEUTICALS, A Division of WYETH, INC.

DEFENDANTS

ANSWER AND AFFIRMATIVE DEFENSES OF CORDIS CORPORATION

Defendant Cordis Corporation ("Cordis") presents the following Answer and Affirmative Defenses to the Complaint:

FIRST DEFENSE

The Complaint fails to state a claim against Cordis upon which relief can be granted.

SECOND DEFENSE - ANSWER

Cordis answers the Complaint, paragraph by paragraph, as follows:

INTRODUCTION

1. Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint and, therefore, denies same.

JURISDICTION AND VENUE

- 2. Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, therefore, denies same.
- 3. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 3 of the Complaint. Cordis admits that it is a foreign corporation with its principal place of business in the State of Florida, and that it has accepted service of process in this action. Cordis

further admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent.

- 4. The allegations contained in paragraph 4 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint and, therefore, denies same.
- 5. The allegations contained in paragraph 5 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint and, therefore, denies same.
 - 6. Omitted from Complaint.
 - 7. Omitted from Complaint.
 - 8. Omitted from Complaint.
- 9. Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and, therefore, denies same.
- 10. The allegations contained in paragraph 10 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and, therefore, denies same.

FACTUAL ALLEGATIONS

- 11. Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint and, therefore, denies same.
 - 12. Cordis denies the allegations contained in paragraph 12 of the Complaint.
 - 13. Cordis denies the allegations contained in paragraph 13 of the Complaint.

- 14. The allegations contained in paragraph 14 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint and, therefore, denies same.
 - Cordis denies the allegations contained in paragraph 15 of the Complaint.
- 16. The allegations contained in paragraph 16 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the Complaint and, therefore, denies same.
- 17. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 17 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003. Cordis further admits that the Cypher Sirolimus-Eluting Coronary Stent uses the drug known as Sirolimus, which is marketed under the trade name Rapamune.
- 18. The allegations contained in paragraph 18 of the Complaint are not directed to Cordis and no response is required. To the extent a response is required, Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint and, therefore, denies same.
- 19. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 19 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003.

- 20. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 20 of the Complaint. Cordis admits that it issued a letter dated July 7, 2003, to healthcare professionals advising that Cordis had received adverse event reports of stent thrombosis occurring at the time of implementation or within a few days of implantation. This letter also advised healthcare professionals to use the Cypher Sirolimus-Eluting Coronary Stent in accordance with the Indications for Use and procedures contained in the package insert.
- 21. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 21 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003. Cordis further admits that in October and November of 2003, the FDA issued "Talk Papers" regarding new information to be considered prior to the use of the Cypher Sirolimus-Eluting Coronary Stent. The "Talk Papers" speak for themselves as to their terms.
- 22. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 22 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003. Cordis further admits that in October and November of 2003, the FDA issued "Talk Papers" regarding new information to be considered prior to the use of the Cypher Sirolimus-Eluting Coronary Stent. The "Talk Papers" speak for themselves as to their terms.
- 23. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 23 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was

approved for sale in the United States in April 2003. Cordis further admits that in April of 2004, the FDA issued a "Warning Letter" regarding the results of the FDA's inspections of Cordis' facilities in the following locations: Miami Lakes, Florida; San German, Puerto Rico; Warren, New Jersey; Roden, Netherlands; Beerse, Belgium; and Latina, Italy. The "Warning Letter" speaks for itself as to its terms.

- Cordis lacks information and knowledge sufficient to form a belief as to the truth of 24. the allegations contained in paragraph 24 of the Complaint and, therefore, denies same.
- The allegations contained in the first sentence of paragraph 25 of the Complaint 25. state a legal conclusion to which no response is required. To the extent a response is required, Cordis admits that it has certain duties imposed on it by law, but denies that it breached any such duties. Cordis denies the remaining allegations contained in paragraph 25 of the Complaint.
 - 26. Cordis denies the allegations contained in paragraph 26 of the Complaint.
 - 27. Cordis denies the allegations contained in paragraph 27 of the Complaint.
 - 28. Cordis denies the allegations contained in paragraph 28 of the Complaint.
 - 29. Cordis denies the allegations contained in paragraph 29 of the Complaint.
 - 30. Cordis denies the allegations contained in paragraph 30 of the Complaint.
 - Cordis denies the allegations contained in paragraph 31 of the Complaint. 31.

FRAUDULENT CONCEALMENT

- 32. Cordis denies the allegations contained in paragraph 32 of the Complaint.
- 33. Cordis denies the allegations contained in paragraph 33 of the Complaint.

CLAIMS FOR RELIEF

First Claim Against All Defendants (Negligence)

- 34. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.
- 35. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 35 of the Complaint. Cordis admit that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003.
- 36. The allegations contained in paragraph 36 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Cordis admits that it has certain duties imposed on it by law, but denies that it breached any such duties. Cordis denies any remaining allegations contained in paragraph 36 of the Complaint.
 - 37. Cordis denies the allegations contained in paragraph 37 of the Complaint.
- 38. Cordis denies the allegations contained in paragraph 38 of the Complaint, including subparagraphs (a) through (n).
 - 39. Cordis denies the allegations contained in paragraph 39 of the Complaint.
 - 40. Cordis denies the allegations contained in paragraph 40 of the Complaint.

Cordis denies the allegations contained at the end of paragraph 40 of the Complaint beginning with the words "As a direct and proximate cause."

Second Claim Against All Defendants (Strict Liability: Failure to Warn)

41. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.

- 42. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 42 of the Complaint. Cordis admit that Cordis designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003.
 - 43. Cordis denies the allegations contained in paragraph 43 of the Complaint.
 - 44. Cordis denies the allegations contained in paragraph 44 of the Complaint.
 - 45. Cordis denies the allegations contained in paragraph 45 of the Complaint.
 - 46. Cordis denies the allegations contained in paragraph 46 of the Complaint.

Third Claim Against All Defendants (Strict Liability: Design Defect)

- 47. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.
- 48. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 48 of the Complaint. Cordis admit that Cordis designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003.
 - 49. Cordis denies the allegations contained in paragraph 49 of the Complaint.
 - 50. Cordis denies the allegations contained in paragraph 50 of the Complaint.
 - 51. Cordis denies the allegations contained in paragraph 51 of the Complaint.
- 52. Cordis lacks information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 52 of the Complaint and, therefore, denies same.
 - 53. Cordis denies the allegations contained in paragraph 53 of the Complaint.
 - 54. Cordis denies the allegations contained in paragraph 54 of the Complaint.

Fourth Claim Against All Defendants (Breach of Implied Warranty)

- 55. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.
- 56. Except as hereinafter expressly admitted, Cordis denies the allegations contained in paragraph 56 of the Complaint. Cordis admits that it designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent. Cordis incorporates the FDA-approved prescribing information for the Cypher Sirolimus-Eluting Coronary Stent which provides indicated uses for the product and which is the best evidence of its own content. Cordis further states that the allegation that they "impliedly warranted their products to be of merchantable quality and safe and fit for their intended use" states a legal conclusion to which no response is required. To the extent a response is required, Cordis admits that it has certain duties imposed on it by law, but denies that it breached any such duties.
 - 57. Cordis denies the allegations contained in paragraph 57 of the Complaint.
 - 58. Cordis denies the allegations contained in paragraph 58 of the Complaint.

Fifth Claim Against All Defendants (Unjust Enrichment)

- 59. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.
 - 60. Cordis denies the allegations contained in paragraph 60 of the Complaint.
 - 61. Cordis denies the allegations contained in paragraph 61 of the Complaint.
 - 62. Cordis denies the allegations contained in paragraph 62 of the Complaint.

DAMAGES

- 63. Cordis incorporates by reference all of the paragraphs of the Answer as if fully set forth herein.
- 64. Cordis denies the allegations contained in paragraph 64 of the Complaint, including subparagraphs (a) through (h).

PRAYER FOR RELIEF

Cordis denies the allegations contained at the end of the Complaint in the two unnumbered paragraphs beginning with the words "WHEREFORE, premises considered." Furthermore, Cordis denies that Plaintiff is entitled to any damages or relief whatsoever against Cordis, whether jointly or severally.

All allegations of the Complaint not heretofore specifically admitted or denied are now denied generally as if such denial were set forth specifically herein. Cordis requests that the Complaint be dismissed, taxing Plaintiff with all costs and Cordis' attorneys' fees herein.

THIRD DEFENSE

At all times material hereto, the Cypher Sirolimus-Eluting Coronary Stent conformed to the state-of-the-art and was not unreasonably dangerous or defective.

FOURTH DEFENSE

To the extent that Jackie L. McConnell's reactions to the Cypher Sirolimus-Eluting Coronary Stent were idiosyncratic reactions, Cordis denies any liability.

FIFTH DEFENSE

The injuries to Jackie L. McConnell, if any, were caused in whole or in part by the acts or omissions of others for whose conduct Cordis is not responsible. The injuries to Jackie L. McConnell, if any, were not caused by any acts or omissions of Cordis.

Page 114 of 128

SIXTH DEFENSE

The injuries to Jackie L. McConnell, if any, were the result of independent, intervening or superseding causes over which Cordis had no control.

SEVENTH DEFENSE

The Cypher Sirolimus-Eluting Coronary Stent was intended for and sold to a knowledgeable and sophisticated user over whom Cordis had no control and who was fully informed of the risks and dangers, if any, associated with the medical device and the precautions, if any, required to avoid those risks and dangers.

EIGHTH DEFENSE

The injuries to Jackie L. McConnell, if any, were the result of pre-existing or subsequent conditions unrelated to the Cypher Sirolimus-Eluting Coronary Stent.

NINTH DEFENSE

The injuries to Jackie L. McConnell, if any, were the result of misuse of the Cypher Sirolimus-Eluting Coronary Stent.

TENTH DEFENSE

If Cordis is found to have made any warranties alleged by Plaintiff (which Cordis specifically denies), Plaintiff's claims for breach of warranty, both expressed and/or implied, are barred by their failure to give notice as required by Tenn. Code Ann. § 47-2-607 and/or because the alleged warranties were disclaimed.

ELEVENTH DEFENSE

Some or all of the damages alleged by Plaintiff are barred by Tenn. Code Ann. § 47-2-714, 715.

TWELFTH DEFENSE

Cordis affirmatively pleads the application of Comment k to the Restatement of Torts (Second) Section 402A and Restatement (Third) Torts: Products Liability Section 6. Cordis provided adequate and complete warnings to Jackie L. McConnell's treating physicians and, therefore, the product was not defective or unreasonably dangerous.

THIRTEENTH DEFENSE

Cordis provided adequate and complete warnings of all risks associated with the subject stent to the medical professionals. Because Cordis adequately warned Jackie L. McConnell's physicians of the risks associated with the medical device, the learned intermediary doctrine bars any recovery.

FOURTEENTH DEFENSE

The applicable statute of limitations and/or the doctrine of laches bar Plaintiff's claims.

FIFTEENTH DEFENSE

Cordis affirmatively pleads Tenn. Code Ann. § 29-11-101 et seq.

SIXTEENTH DEFENSE

To the extent that Plaintiff's claims are based upon any theory of product liability, they are barred or limited by Tennessee's Product Liability Act, Tenn. Code Ann. § 29-28-101 et seq., and Crodis affirmatively asserts all defenses available therein.

SEVENTEENTH DEFENSE

Jackie L. McConnell knew or should have known of any risk associated with the Cypher Sirolimus-Eluting Coronary Stent; therefore, the doctrine of assumption of the risk may bar or diminish any recovery.

EIGHTEENTH DEFENSE

To the extent that Plaintiff's claims are based upon any theory providing for liability without proof of causation by Cordis, they violate Cordis' rights under the United States Constitution and the Constitution of the State of Tennessee.

NINETEENTH DEFENSE

Plaintiff failed to mitigate any alleged damages.

TWENTIETH DEFENSE

Plaintiff's claims are barred because Cordis complied with the applicable statutes and with the requirements and regulations of the Food and Drug Administration.

TWENTY-FIRST DEFENSE

The United States Food and Drug Administration ("FDA") regulates medical devices, including the Cypher Sirolimus-Eluting Coronary Stent, and has approved the medical device, as well as the accompanying labeling, as safe and effective. Accordingly, Plaintiff's claims, predicated on state tort law and alleging the subject stent to be unsafe, conflict with the FDA's safety decisions and are pre-empted by the Supremacy Clause of the United States Constitution, the Food, Drug and Cosmetic Act, and the Medical Device Amendments of 1976, 21 U.S.C. Section 360 et seq.

TWENTY-SECOND DEFENSE

Plaintiff's claims for punitive damages cannot be sustained because due process requires that the standard of liability for determining whether punitive damages are warranted requires that defendants have participated in intentional, malicious, fraudulent or reckless conduct or have actual knowledge of malicious conduct, and Tennessee law does not provide such an instruction in violation of Cordis' due process rights guaranteed by the Fourteenth Amendment of the United States Constitution and Article 1, Section 8 of the Constitution of the State of Tennessee.

TWENTY-THIRD DEFENSE

Plaintiff's claims for punitive damages cannot be sustained because Tennessee law permits the application of joint and several liability for punitive damages, which violates Cordis' due process and equal protection rights guaranteed by the Fourteenth Amendment of the United States Constitution and Article 1, Section 8 of the Constitution of the State of Tennessee.

TWENTY-FOURTH DEFENSE

To the extent Plaintiff seeks punitive damages, these sanctions must be limited by Cordis' relevant economic activity in the State of Tennessee.

TWENTY-FIFTH DEFENSE

An award of punitive damages without bifurcating the trial as to all alleged punitive damages would violate Defendant's due process rights and therefore Defendant moves for bifurcation on the issue of punitive damages.

TWENTY-SIXTH DEFENSE

Cordis reserves the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

TWENTY-SEVENTH DEFENSE

Plaintiff's fraud and misrepresentation claims are barred because Plaintiff did not assert the fraud allegations with particularity as required by both Rule 9 of the Federal and Tennessee Rules of Civil Procedure.

TWENTY-EIGHTY DEFENSE

Cordis incorporates any applicable affirmative defense or other defenses asserted by any other defendant in this action.

WHEREFORE, PREMISES CONSIDERED, Cordis Corporation demands that the Complaint against it be dismissed with prejudice with all costs taxed to Plaintiff.

DATED this the 3 day of December, 2004.

Respectfully submitted,

ATTORNEY FOR CORDIS CORPORATION

OF COUNSEL:

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC P.O. Box 171443 Memphis, Tennessee 38187-1443

Ph: (901) 680-7327

Fax: (901) 680-7201

CERTIFICATE OF SERVICE

I, Charles C. Harrell, one of the attorneys for Cordis Corporation, do hereby certify that I have this day served a true and correct copy of the above and foregoing Answer and Affirmative Defenses of Cordis Corporation by mailing same via United States Mail, postage fully prepaid thereon, to the following:

Berry Cooper, Esq. (No. 13196) Deal, Cooper & Holton, PLLC 296 Washington Avenue Memphis, TN 38103

ATTORNEYS FOR PLAINTIFF

James M. Doran, Jr., Esq. Waller Lansden Dortch & Davis, PLLC Nashville City Center 511 Union Street, Suite 2700 Nashville, TN 37219

ATTORNEYS FOR SURMONDICS, INC.

Samuel L. Felker, Esq. Timothy R. Johnson, Esq. Bass Berry & Sims, PLC 315 Deadrich Street AmSouth Center, Suite 2700 Nashville, TN 37238-3001

ATTORNEYS FOR WYETH

So certified, this the **3vd** day of December, 2004.

JACKSON 984879v1

EXHIBIT 10

Case 2:04-cv-02005-CJB Document 1 Filed 07/16/2004 Page 1 of 26
United States District Court

Eastern District of Louisiana

Tantillo

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CIVIL ACTION NO. 2:04-cv-02005/J/1

Cordis Corporation

The record reflects that a Notice of Removal has been filed in the captioned case; accordingly,

Pursuant to 28 U.S.C. 1447(b), the removing party is directed to file within 10 days:

- (1) A list of all parties still remaining in this action;
- (2) Copies of all pleadings, including answers, filed by those parties in state court; and
- (3) Copies of the return on service of process on those parties filed in state court.

New Orleans, Louisiana, July 20, 2004.

By Direction of the Court

LORETTA G. WHYTE, CLERK

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Case 2:04-cv-02005-CJB

Document 1

Filed 07/16/2004

Page 2 of 26



UNITED STATES DISTRICT COURT EASTERN DISTRICT OF LOUISIANA

TAMMY E. TANTILLO, INDIVIDUALLY, AS ADMINISTRATRIX OF THE ESTATE OF JOSEPH S. TANTILLO, JR. AND AS NATURAL TUTRIX OF THE MINORS, HEATHER MAY TANTILLO AND TYLER JOSEPH TANTILLO

CIVIL ACTIONNO. 2005

JUDGESECT. J MAG. 1

VERSUS

CORDIS CORPORATION AND ST. TAMMANY PARISH HOSPITAL

MAGISTRATE

NOTICE OF REMOVAL

TO: THE JUDGES OF THE UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF LOUISIANA

Pursuant to 28 U.S.C. § 1446, Defendant, Cordis Corporation, with full reservation of any and all defenses, objections, and exceptions, provides Notice of Removal of this civil action to the United States District Court for the Eastern District of Louisiana, and respectfully represents that:

1.

On May 24, 2004, plaintiff, Tammy E. Tantillo, individually, as administratrix of the estate of Joseph S. Tantillo, Jr. and as natural tutrix of the minors, Heather May Tantillo and Tyler Joseph

1

Fee F/SO.

Process
X Dktd Caa

CtRmDep

Doc. No. 1

Case 2:04-cv-02005-CJB

Document 1

Filed 07/16/2004

Page 3 of 26

Tantillo, commenced an action against Cordis Corporation and St. Tammany Parish Hospital in the 22nd Judicial District Court for the Parish of St. Tammany, State of Louisiana, entitled "Tammy E. Tantillo, individually, as administratrix of the estate of Joseph S. Tantillo, Jr. and as natural tutrix of the minors, Heather May Tantillo and Tyler Joseph Tantillo v. Cordis Corporation and St. Tammany Parish Hospital," No. 2004-12478, on the docket of said court.

2.

Service of process was effected on Cordis Corporation by certified mail on June 16, 2004, pursuant to the Louisiana Long Arm Statute, La. Rev. Stat. § 13:3201, et seq. Pursuant to 28 U.S.C. § 1446(a), the entire state court record is attached as Exhibit "A" to this Notice of Removal.

3.

As will be shown more fully below, this Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a), as the amount in controversy, exclusive of interest and costs, exceeds the sum of \$75,000.00, and there is complete diversity of citizenship between the plaintiff and the only nonfraudulently joined defendant, Cordis Corporation. Thus, this action may be removed to this Court pursuant to the provisions of 28 U.S.C. § 1441.

4.

Plaintiff, Tammy E. Tantillo, individually, as administratrix of the estate of Joseph S. Tantillo, Jr. and as natural tutrix of the minors, Heather May Tantillo and Tyler Joseph, is and was at the time the state court action was commenced a citizen of the State of Louisiana. See Exhibit A, Petition, prefatory ¶.

5.

Cordis Corporation is a Florida corporation with its principal place of business in Florida.

Cordis Corporation was not, at the time this action was filed, and still is not a citizen of the State of Louisiana.

6.

Cordis Corporation avers that plaintiff has improperly and fraudulently joined as a defendant St. Tammany Parish Hospital, sometimes appearing as "St. Tammany Parish Hospital Service District No. 1" (hereinafter "hospital"), which is and was at the time of this action was commenced a political subdivision of the State of Louisiana and a citizen of the State of Louisiana, for the sole and only purpose of attempting to defeat or prevent removal of this cause to the United States District Court for the Eastern District of Louisiana. As will more fully appear upon an inspection of the pleadings, plaintiff has wholly failed to show any claim for relief or right of recovery against the hospital.

7.

This lawsuit arises out of an April 24, 2003 operative procedure undergone by Joseph S. Tantillo, Jr. at St. Tammany Parish Hospital. During this procedure, a TrapEase Permanent Vena Cava Filter (hereinafter "filter") manufactured by Cordis Corporation was allegedly inserted into Mr. Tantillo's vena cava. Petition, ¶ 5, 6. The filter is an FDA-approved device used to help prevent pulmonary embolism. Subsequent to this procedure, Mr. Tantillo purportedly suffered fatigue and swelling of his extremities, and died on June 16, 2004. The death certificate attached to the Petition indicates the cause of death as "exsanguination due to perforation of [inferior vena cava] due to" the filter. *Id.*, Exhibit "B" to Petition.

8.

The only claim specifically asserted in the Petition against the hospital is "that the negligence of St. Tammany Parish Hospital as a 'Seller' of a defective product in violation of Louisiana Products Liability Act caused or contributed to the death of Joseph S. Tantillo, Jr." *Id.*, ¶ 10.

9.

Based on the foregoing allegation, the Petition fails to set forth any facts that state a legally cognizable claim against the hospital under the Louisiana Products Liability Act, La. Rev. Stat. § 9:2800.51 et seq. (hereinafter "LPLA"). The LPLA sets forth the "exclusive theories of liability for manufacturers for damages caused by their products." La. Rev. Stat. § 9:2800.52 (emphasis added). The hospital does not fall within the definition of "manufacturer" as set forth in the LPLA, because, upon information and belief, the hospital is not "in the business of manufacturing" the filter; does not label the filter as its own or otherwise hold itself out to be the manufacturer of the filter; does not exercise control over or influence a characteristic of the design, construction or quality of the filter; did not incorporate into the filter a component or part of another manufacturer, or incorporate the filter into another product; and is not the alter ego of an alien manufacturer. Id. § 9:2800.53(1)(a)-(d). The Petition therefore fails to state a viable cause of action against the hospital under the LPLA.

10.

Moreover, even construing the allegations as broadly as the Petition will allow, the Petition fails to set forth any facts that would support a cause of action in "negligence" against the hospital. In Louisiana, a non-manufacturer seller can only be held liable for damages in tort if it knew or should have known that the product was defective and failed to notify the purchaser of the defect. *Kelly v. Price-Macemon, Inc.*, 992 F.2d 1408, 1413 (5th Cir. 1993); *Tauzier v. Dodge*, No. 97-2444,

1998 WL 458184, *4 (E.D. La. Aug. 4, 1998) (and cases cited therein). The Petition contains no allegations that suggest that the hospital knew or should have known of a defect in the filter. Moreover, upon information and belief, the hospital did not know and had no way of knowing whether or not the filter used in Mr. Tantillo's April 24, 2003 medical procedure contained a defect., particularly because the filter is packaged in a sterilized pouch and not opened until just prior to insertion in the patient by the surgeon.

11.

Plaintiff therefore has no possibility of prevailing on the merits of her claim against the hospital, and this defendant's citizenship should be disregarded.

12.

The right to remove a diversity action cannot be defeated by the fraudulent joinder of a resident defendant against whom no claim could be stated under state law. *Chesapeake and Ohio Ry. v. Cockrell*, 232 U.S. 146, 152, 34 S.Ct. 278, 280, 58 L.Ed. 544 (1914); *Burden v. General Dynamics Corp.*, 60 F.2d 213, 216 (5th Cir. 1995). Accordingly, the citizenship of defendant, St. Tammany Parish Hospital, must be ignored for the purposes of diversity jurisdiction. *Burden*, 60 F.2d at 218.

13.

The removing party need not obtain the consent of fraudulently joined co-defendants. Jernigan v. Ashland Oil, Inc., 989 F.2d 812, 815 (5th Cir. 1993), cert. denied, 510 U.S. 868 (1993). Therefore, the consent of the hospital is not necessary for this matter to be properly removed. Case 2:04-cv-020<u>05</u>-CJB

Document 1

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14.

Therefore, complete diversity exists between Plaintiff and Cordis Corporation, the only nonfraudulently joined defendant.

15.

The monetary jurisdictional prerequisite to federal jurisdiction under 28 U.S.C. § 1332(a) is satisfied. The Petition for Damages alleges that Mr. Tantillo died because the filter "was unreasonably dangerous in its design and manufacturing," that he suffered "extreme and excruciating pain prior to his death," and seeks damages for "his pain and suffering prior to his death." The Petition further seeks damages for the plaintiff, individually and as natural tutrix of the minors, Heather Tantillo and Tyler Tantillo, for "loss of consortium, loss of support, mental anguish and grief, as well as medical and funeral expenses." Id., ¶ 12. It is therefore facially apparent that the amount in controversy exceeds \$75,000, exclusive of interest and costs. Luckett v. Delta Airlines. Inc., 171 F.3d 295, 298 (5th Cir. 1999).

16.

Therefore, based on the allegations of the Petition, the amount-in-controversy requirement of 28 U.S.C. 1332(a) is met.

17.

This Notice of Removal is being filed within thirty days of service on Cordis Corporation, the only non-fraudulently joined defendant, and is thus timely filed under 28 U.S.C. § 1446(b).

18.

Defendant will promptly serve written notice of the filing of this Notice of Removal with the Clerk of Court for the 22nd Judicial District Court for the Parish of St. Tammany, State of Louisiana. Case 2:04-cv-02005-CJB

Document 1

Filed 07/16/2004

Page 8 of 26

WHEREFORE, Defendant, Cordis Corporation, prays that the above numbered and entitled cause on the docket of the 22nd Judicial District Court for the Parish of St. Tammany, State of Louisiana, be removed from that court to the docket of the United States District Court for the Eastern District of Louisiana.

Respectfully submitted,

IRWIN FRITCHIE URQUHART & MOORE LLC

BY:

James B. Irwin, T.A. (La. Bar No. 7172)

Monique M. Gársaud (La., Bar No. 25393)

Stephanie Lottinger Irwin (La. Bar No. 22493)

400 Poydras Street

Suite 2700

New Orleans, Louisiana 70130

Telephone: (504) 310-2100

Attorneys for Cordis Corporation

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing pleading has been served upon counsel for all parties to this proceeding by mailing a copy of same to each by U.S. Mail, properly addressed and postage prepaid, on this 4 day of July, 2004.

EXHIBIT 11

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TENNESSEE

	——, ZBUJ APR 30 P 3: 45
ALEXANDER A. STRATIENKO, M.D.,	U.S. DISTRICT COURT EASTERN DIST, TENN.
Plaintiff,	BY_ DEP. CLEBK
V.) No. 1:02-CV 005
CORDIS CORPORATION,) Edgar/Powers
Defendant.) ANSWER
)

DEFENDANT CORDIS CORPORATION'S ANSWER TO PLAINTIFF STRATIENKO'S AMENDED COMPLAINT

Defendant CORDIS CORPORATION ("Defendant" or "Cordis") answers the Plaintiff's Amended Complaint as follows:

- Cordis is without sufficient information to form a belief as to the truth of the 1. allegations in paragraph 1 and therefore denies the allegations in paragraph 1.
- Cordis admits that it is a Florida Corporation and that it may be served with 2. process via its registered agent in Plantation, Florida. Cordis denies that its principal place of business is in Warren, New Jersey. Cordis' principal place of business is in Miami Lakes, Florida.
- Cordis admits that it has business contacts in Hamilton County, Tennessee. The 3. allegations regarding jurisdiction and venue call for legal conclusions and do not require a response. Cordis is without sufficient information to form a belief as to the truth of the remaining allegations in paragraph 3 and therefore denies the remaining allegations in paragraph 3,

- 4. Cordis is without sufficient information to form a belief as to the truth of the allegations of paragraph 4 and therefore denies the allegations in paragraph 4.
- 5. Cordis admits that one of its employees signed the document attached as <u>Exhibit</u>

 <u>A</u> to the Amended Complaint. The document speaks for itself. Cordis denies the remaining allegations in paragraph 5.
- 6. Cordis is without sufficient information to form a belief as to the truth of the allegations of paragraph 6 and therefore denies the allegations in paragraph 6.
- 7. Cordis admits that Cordis advised Plaintiff that it had no interest in his product.
 Cordis denies that this lack of interest in Plaintiff's "Product" was limited to a particular time or time period.
 - 8. Denied.
- 9. Cordis is without sufficient information to form a belief as to the truth of the allegations of paragraph 9 regarding Plaintiff's knowledge or state of mind and therefore denies such allegations in paragraph 9. To the extent that paragraph 9 alleges any wrongdoing by Cordis, Cordis denies such allegations of paragraph 9.
 - 10. Denied.
- 11. Cordis admits that on or about March 2, 2001, Cordis received a letter from Plaintiff's counsel concerning the issues giving rise to the instant litigation. Cordis denies the allegations set forth in the substance of that letter.
- 12. Cordis admits that Plaintiff is the inventor listed in U.S. Patent No. 6,245,045 B1. Cordis denies this Patent is valid.

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- 13. Cordis is without information sufficient to form a belief as to the truth of the allegations in paragraph 13 and therefore denies the allegations in paragraph 13.
- 14. Cordis admits that it does business in this district. Cordis denies the remaining factual allegations in paragraph 14. To the extent that paragraph 14 asserts an legal conculsion, no response is required of Cordis at this time.
 - 15. Denied. Cordis began selling the Vistabrite Tip IG in 2000.
 - 16. Denied.
 - 17. Denied.
 - 18. Denied.
 - 19. Denied.
 - 20. Denied.
- 21. Cordis reasserts its responses to the allegations contained in paragraphs 1 through 20 of the Amended Complaint as if fully set forth herein.
 - 22. Denied.
 - 23. Denied.
- 24. Cordis reasserts its responses to the allegations contained in paragraphs 1 through 23 of the Amended Complaint as if fully set forth herein.
 - 25. Denied.
 - 26. Denied.

- 27. Cordis reasserts its responses to the allegations contained in paragraphs 1 through 26 of the Amended Complaint as if fully set froth herein.
 - 28. Denied.
 - 29. Denied.
 - 30. Denied.
- 31. Cordis reasserts is responses to the allegations contained in paragraph 1 through 30 of the Amended Complaint as if fully set forth herein.
 - 32. Denied.
 - 33. Denied.
 - 34. Denied.
- Cordis denies that Plaintiff is entitled to any of the relief sought in the Amended 35. Complaint.

AFFIRMATIVE AND OTHER DEFENSES

Cordis states the following defenses without assuming the burden of proof as to any issue that otherwise would rest upon Plaintiff.

- The Complaint fails to state a claim upon which relief can be granted. 1.
- 2. Plaintiff's claims are barred, in whole or in part, by laches.
- 3. Plaintiff's claims are barred, in whole or in part, by the equitable doctrine of estoppel.
- 4. Plaintiff's claims are barred, in whole or in part, by waiver.
- 5. Plaintiff has failed to mitigate his damages, if any.

- 6. Plaintiff's requested relief, if any should be awarded, is limited to an amount of damages no greater than a fair, reasonable and nondiscriminatory license amount.
- 7. Plaintiff's Patents are invalid under the doctrine of obviousness.
- 8. Plaintiff's Patents are invalid because Cordis was first to invent.
- 9. Plaintiff's Patents are invalid because of inequitable conduct regarding the Patent offices.
- 10. Plaintiff's claims are barred, in whole or in part, by the doctrines of unclean hands.
- 11. Plaintiff's claims are barred in whole or in part under the doctrine of patent misuse.
- 12. Plaintiffs claims are barred, in whole of in part, because Cordis does not infringe.

Of Counsel:

Kathryn A. Meisel JOHNSON & JOHNSON One Johnson & Johnson Plaza New Brunswick, NJ 08935

- Dated: April 28, 2003

Douglas M. Campbell (Tenn. BPR #5634)

Campbell & Campbell Suite 1200 James Building

735 Broad Street

Chattanooga, Tennessee 37402-1835

(423) 266-1108

Richard A. Ripley

HOWREY SIMON ARNOLD & WHITE, LLP

1299 Pennsylvania Avenue, N.W.

Washington, D.C. 20004

(202) 783-0800

Attorneys for CORDIS CORPORATION

CERTIFICATE

I certify that an exact copy of this document has been served upon all parties by properly mailing or hand delivering same to:

John P. Konvalinka, Esq. Mathew D. Brownfield, Esq. GRANT, KONVALINKA & HARRISON, PC 633 Chestnut Street, Suite 900 Chattanooga, TN 37450-0900

This the 30 day of April , 2003.

CAMPBELL & CAMPBELL

EXHIBIT 12

Case 1:02-cy-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 1 of 7

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA MIAMI DIVISION

CASE NO. 02-22555-CIV-HUCK MAGISTRATE JUDGE TURNOFF

ARLA	INE	&	GINA	RO	CKEY,	INC
2 44 244			~ 11 11 t		~~~~~	

Plaintiff,

vs.

CORDIS CORPORATION,

Defendant.

ANSWER

Cordis Corporation ("Cordis"), through its attorneys, for its Answer to the Complaint of Arlaine & Gina Rockey, Inc. ("AGRI") alleges as follows:

- 1. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1.
- Denies the allegations contained in paragraph 2, except admits that Cordis is a
 Florida corporation having a principal place of business at 14201 N.W. 60th Avenue, Miami
 Lakes, Florida.
- 3. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3.
- 4. Denies the allegations contained in paragraph 4, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegation that Dr. Rockey filed his first U.S. patent application on or about June 2, 1978.



Case 1:02-cv-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 2 of 7

- 5. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 5, except admits that the PTO issued the patents mentioned in paragraph 5.
- 6. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 6.
- 7. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 7.
- 8. Denies the allegations in paragraph 8, except admits that in or about 1994 AGRI began to negotiate with Cordis.
 - 9. Admits the allegations contained in paragraph 9.
- 10. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 10.
- Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 11, except admits that a copy of the May 16, 1995 License Agreement is attached to the Complaint as Exhibit B.
 - 12. Admits the allegations contained in paragraph 12.
 - 13. Denies the allegations contained in paragraph 13.
- 14. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 14, except admits that any obligation of Cordis to pay a Running Royalty would not begin until after Cordis had sold in excess of \$20,000,000 worth of products covered by the Rockey Patents.

Case 1:02-cv-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 3 of 7

- 15. Denies the allegations contained in paragraph 15, except admits that Cordis has not paid any Running Royalty to AGRI because Cordis does not owe any Running Royalty to AGRI.
- 16. Denies the allegations contained in paragraph 16, and refers to the License Agreement for its terms and conditions.
- 17. Denies the allegations contained in paragraph 17, except admits that in or about early 1996 Cordis became a Johnson & Johnson ("J&J") company.
 - 18. Denies the allegations contained in paragraph 18.
- 19. Denies the allegations contained in paragraph 19, except admits that Cordis sells a product called the Palmaz® Balloon-Expandable Stent.
 - 20. Denies the allegations contained in paragraph 20.
- 21. Repeats and realleges the responses set forth in paragraphs 1-20, <u>supra</u>, with the same force and effect as if fully set forth herein.
- 22. Denies the allegations contained in paragraph 22, and refers to the License Agreement for its terms and conditions.
- 23. Denies the allegations contained in paragraph 23, except admits that Cordis has not paid any Running Royalty to AGRI because Cordis does not owe any Running Royalty to AGRI.
 - 24. Denies the allegations contained in paragraph 24.
 - 25. Denies the allegations contained in paragraph 25.
 - 26. Denies the allegations contained in paragraph 26.
- 27. Denies the allegations contained in paragraph 27, except admits that Cordis has not extended the life of any of the Rockey Patents.

Case 1:02-cv-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 4 of 7

- 28. Denies the allegations contained in paragraph 28.
- 29. Denies the allegations contained in paragraph 29.
- 30. Repeats and realleges the responses set forth in paragraphs 1-20, <u>supra</u>, with the same force and effect as if fully set forth herein.
- 31. Denies the allegations contained in paragraph 31, and refers to the License Agreement for its terms and conditions.
 - 32. Denies the allegations contained in paragraph 32.
 - 33. Denies the allegations contained in paragraph 33.
- 34. Denies the allegations contained in paragraph 34, except admits that Cordis has not sold Licensed Products.
 - 35. Denies the allegations contained in paragraph 35.
 - 36. Denies the allegations contained in paragraph 36.
- 37. Repeats and realleges the responses set forth in paragraphs 1-20, supra, with the same force and effect as if fully set forth herein.
 - 38. Denies the allegations contained in paragraph 38.
- 39. Denies the allegations contained in paragraph 39, except admits that paragraph 14.9 of the License Agreement provides that Cordis may attempt to obtain a term extension for the Patents.
 - 40. Denies the allegations contained in paragraph 40.
 - 41. Denies the allegations contained in paragraph 41.
 - 42. Denies the allegations contained in paragraph 42.
 - 43. Denies the allegations contained in paragraph 43.

Case 1:02-cv-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 5 of 7

CORDIS' FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

CORDIS' SECOND AFFIRMATIVE DEFENSE

AGRI's claims are barred under the doctrines of laches, waiver and estoppel.

CORDIS' THIRD AFFIRMATIVE DEFENSE

AGRI's claims are barred in whole or in part under the statute of limitations.

CORDIS' FOURTH AFFIRMATIVE DEFENSE

Neither Cordis nor its "affiliates" (as that term is used in the licensing agreement between AGRI and Cordis) make, sell, or offer for sale any product that is covered by the Rockey Patents.

WHEREFORE, defendant Cordis respectfully requests that this Court enter judgment in its favor and against plaintiff AGRI:

- (a) Dismissing the Complaint with prejudice and entering judgment in Cordis' favor;
- (b) Awarding Cordis the costs and attorneys' fees for this action;

Case 1:02-cv-22555-CMA Document 11 Entered on FLSD Docket 10/01/2002 Page 6 of 7

(c) Awarding Cordis such other and further relief as this Court deems just and proper.

Dated: September 30, 2002

Of Counsel:

Eugene M. Gelernter
Peter Widulski
PATTERSON, BELKNAP
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1133 Avenue of the Americas
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(212) 337-2000

Tracy Poole
Johnson & Johnson Law Department
One Johnson & Johnson Plaza
New Brunswick, NJ 08543

Respectfully submitted,

ARAGON, BURLINGTON, WEIL & CROCKETT, P.A.

Rudolph F. Aragon

Florida Bar No. 286249

Kevin C. Kaplan Florida Bar No. 933848

Office in the Grove, Penthouse 2699 South Bayshore Drive

Miami, Florida 33133

Telephone: (305) 858-2900 Attorneys for Defendant Cordis

Corporation

Document 11 Entered on FLSD Docket 10/01/2002 Page 7 of 7 Case 1:02-cv-22555-CMA

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served via facsimile and U.S. Mail this 300 day of September, 2002, upon the following:

Harvey W. Gurland, Jr., Esq. James A. Weinkle, Esq. Duane Morris LLP **Suite 3400** 200 South Biscayne Boulevard Miami, Florida 33131 Counsel for Plaintiff

Frederick A. Tecce, Esq. Anthony J. DiMarino, III, Esq. McShea/Tecce, P.C. The Mellon Bank Center – 16th Floor 1735 Market Street Philadelphia, PA 19103 Co-counsel for Plaintiff

By: MM My
Rudolph F. Aragon

EXHIBIT 13

Filed 06/07/2002 Page 1 of 5 Case 2:02-cv-00959-WMA Document 4

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ALABAMA 02 JUN -7 AM 11: 12 SOUTHERN DIVISION U.S. DISTRICT COURT WILLIAM KAN, N.D. OF ALABAMA) Plaintiff, Case No. CV-02-AR-0959-S vs. Judge William M. Acker, Jr. CORDIS CORPORATION and BAPTIST HEALTH SYSTEM, INC. d/b/a BAPTIST **ANSWER** MONTCLAIR HOSPITAL)) Defendants.

ANSWER

For its Answer to the Complaint filed by Plaintiff William Kan ("Kan"), Cordis Corporation ("Cordis") answers and responds as follows:

- 1. Cordis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint and therefore denies the same.
 - 2. Admitted.
- 3. Cordis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint and therefore denies the same.
- Cordis admits that this Court has jurisdiction over this action, but denies 4. that Kan has a cause of action under 35 U.S.C. § 281, or otherwise.



- 5. Cordis admits that United States Patent No. 5,147,282 ("the '282 patent"), entitled "Irradiation Loading Apparatus," states on its face that it was issued by the United States Patent and Trademark Office on September 15, 1992, to William Kan. Cordis is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 5 of the Complaint and therefore denies the same.
 - 6. Denied.
 - 7. Denied.
- 8. Cordis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of the Complaint and therefore denies the same.
- 9. Cordis admits that it sells a comprehensive intravascular brachytherapy system called the CheckmateTM System. Cordis denies that the CheckmateTM System, or any device otherwise named or designated and sold by Cordis, infringes the '282 patent. Cordis is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 9 of the Complaint and therefore denies the same.
- 10. Cordis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of the Complaint and therefore denies the same.

Case 2:02-cv-00959-WMA

Document 4

Filed 06/07/2002 Page 3 of 5

AFFIRMATIVE DEFENSES

- As a separate defense, and solely by way of an alternative defense and not 1. to be construed as an admission, the '282 patent is invalid for failing to meet the statutory and decisional requirements for patentability, including those of 35 U.S.C. §§ 102, 103, and/or 112.
- As a separate defense, and solely by way of an alternative defense and not 2. to be construed as an admission, Cordis's activities in making, using, selling and/or offering for sale in the United States comprehensive intravascular brachytherapy system products do not infringe any claim of the '282 patent.
- On information and belief, plaintiff is barred from obtaining relief for any 3. or all infringement of the '282 patent for failure to satisfy the notice requirements of 35 U.S.C. § 287.

WHEREFORE, Defendant prays that this Court dismiss Plaintiff's Complaint in its entirety with prejudice, award judgment for the Defendant on the Complaint, declare this case to be an exceptional case under 35 U.S.C. § 285 and award Defendant its attorneys fees, and grant Defendant such other and further relief as the Court deems just and proper.

Case 2:02-cv-00959-WMA Document 4 Filed 06/07/2002 Page 4 of 5

CORDIS CORPORATION

One of its Attorneys

Dated: June 7, 2002

Lawrence B. Clark Lange, Simpson, Robinson & Somerville LLP 2100 3rd Avenue North Birmingham, Alabama 35203-3367 Telephone: (205) 250-5050

SIDLEY AUSTIN BROWN & WOOD David T. Pritikin (Pro Hac Vice) Hugh A. Abrams (Pro Hac Vice) 10 South Dearborn Street Chicago, Illinois 60603 Telephone: (312) 853-7000

Facsimile: (312) 853-7036

Facsimile: (205) 250-5034

CORDIS CORPORATION Eric I. Harris (Of Counsel) One Johnson & Johnson Plaza New Brunswick, New Jersey 08933 Telephone: (732) 524-2444 Facsimile: (732) 524-2788

Attorneys for Defendant Cordis Corporation

CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing has been served upon the following listed persons via hand delivery on this the _____ day of June, 2002:

Kenneth Lee Cleveland, Esq. Cleveland & Cleveland, P.C. 2330 Highland Avenue South Birmingham, AL 35205

Thomas A. Kendrick, Esq. Norman, Wood, Kendrick & Turner Liberty National Building, Suite 1500 2001 3rd Avenue, South Birmingham, AL 35233-2139

Of Counsel

EXHIBIT 14

Document 1

Filed 04/17/2002

Page 1 of 3

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA SOUTHERN DIVISION

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William Kan,	N.D. OF ALABAMA	
Plaintiff,) }	
vs.	Case Number:	
Cordis Corporation and Baptist Health System, Inc. d/b/a Baptist Montclair Hospital,)) CV-02-AR-0959-S	
Defendants.)	

COMPLAINT

- 1. Plaintiff, William Kan is a resident of Dothan, Alabama.
- 2, Cordis Corporation is a corporation believed to be a subsidiary of Johnson & Johnson, Inc. and have its principle place of business in Florida.
- Baptist Health Systems, Inc. is doing business as Baptist Montclair Hospital, is 3. incorporated in Jefferson County, Alabama, and has its principle place of business is located in Jefferson County, Alabama.
- This court has jurisdiction of this action under 28 U.S.C. §1331 because the cause of 4. action arises under 35 U.S.C. §281 providing a civil action as the remedy for infringement of a patent issued by the United States Patent & Trademark Office.
- 5. On September 15, 1992, the United States Patent & Trademark Office issued patent number 5,147,282 to plaintiff, William Kan. This patent is on a medical device entitled Irradiation Loading Apparatus. All maintenance fees have been paid and this patent is in full force and effect.

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Filed 04/17/2002 Page 2 of 3 Case 2:02-cv-00959-WMA Document 1

6. Cordis Corporation makes (manufactures) and sells an infringing device in violation of plaintiff's exclusive right under his patent to make, use, and sell the patented invention claimed therein.

- 7. Cordis Corporation sold or leased or otherwise permitted Baptist Health System, Inc. d/b/a Baptist Montclair Hospital to use an infringing device manufactured by Cordis Corporation in violation of plaintiff's exclusive right under his patent to sell and use the patented invention claimed therein.
- 8. Baptist Health System, Inc. d/b/a Baptist Montclair Hospital is using an infringing device at its hospital in Jefferson County, Alabama in violation of plaintiff's exclusive right under his patent to use the invention claimed therein.
- On information and belief the Cordis CheckmateTM Intravascular Gamma 9. Brachytherapy System is the name and identification of the infringing device used by defendant, Baptist Health System, Inc. d/b/a Baptist Montclair Hospital and sold by defendant, Cordis Corporation, Cordis Corporation may have other names and designations of infringing devices.
- 10. Plaintiff has not given Cordis Corporation or Baptist Health System, Inc. d/b/a Baptist Montclair Hospital authority to make, use, or sell his patented invention.

WHEREFORE, plaintiff, William Kan, demands judgment against Cordis Corporation for all damages permitted under 35 U.S.C. §284 including lost sales, the infringer's profits, triple damages, attorney fees under 35 U.S.C. §285, and an injunction prohibiting Cordis Corporation from future infringement of the patent. William Kan demands judgment against Baptist Health System, Inc. d/b/a Baptist Montclair Hospital for damages permitted under 35 U.S.C. § 284 including a Case 2:02-cv-00959-WMA

Document 1

Filed 04/17/2002

Page 3 of 3

reasonable royalty. William Kan also requests any other relief that is permitted by law or equity based on the facts found at the trial of this cause.

Kenneth Lee Cleveland Attorney for William Kan

Cleveland & Cleveland, P. C.

2330 Highland Avenue South Birmingham, Alabama 35205 (205) 322-1811 (205) 322-1848 (fax)

E-mail: ClevelandAtty@hotmail.com

Plaintiff demands jury trial.

Kenneth Lee Cleveland

Please serve defendants at:

Cordis Corporation A Johnson & Johnson Company 14201 NW 60th Avenue Miami Lakes, FL 33014

Baptist Montclair Hospital c/o Baptist Health System, Inc. Dan R. Hudson, Registered Agent 1509 First National Bldg. Birmingham, Alabama 35203

EXHIBIT 15

Douglas M. Campbell (Tenn. BPR #5634) Campbell & Campbell Suite 1200 James Building 735 Broad Street Chattanooga, Tennessee 37402-1835 (423) 266-1108

Richard A. Ripley
LaTisha S. Gotell
HOWREY SIMON ARNOLD & WHITE, LLP
1299 Pennsylvania Avenue, N.W.
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(202) 783-0800

Attorneys for CORDIS CORPORATION

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DEP. OLERK

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TENNESSEE

	·····
ALEXANDER A. STRATIENKO, M.D.,))
Plaintiff,)
٧.	Docket No. 1:02-CV 005
CORDIS CORPORATION,) ANSWER
Defendant.)
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DEFENDANT CORDIS CORPORATION'S ANSWER TO PLAINTIFF STRATIENKO'S COMPLAINT

Defendant CORDIS CORPORATION ("Defendant" or "Cordis") answers the allegations of the Complaint filed by ALEXANDER A. STRATIENKO, M.D. ("Plaintiff") in the above-captioned action as follows:

1. Cordis is without sufficient information to form a belief as to the truth of the allegations in paragraph 1 and therefore denies the allegations in paragraph 1.

- 2. Cordis admits that it is a Florida Corporation and that it may be served with process via its registered agent in Plantation, Florida. Cordis denies that its principal place of business is in Warren, New Jersey. Cordis' principal place of business is in Miami Lakes, Florida.
- Cordis admits that it has business contacts in Hamilton County, Tennessee. The 3. allegations regarding jurisdiction and venue call for legal conclusions and do not require a response. Cordis is without sufficient information to form a belief as to the truth of the remaining allegations in paragraph 3 and therefore denies the remaining allegations in paragraph 3.
- Cordis is without sufficient information to form a belief as to the truth of the 4. allegations of paragraph 4 and therefore denies the allegations in paragraph 4.
- Cordis admits that one of its employees signed the document attached as Exhibit 5. A to the Complaint. The document speaks for itself. Cordis denies the remaining allegations in paragraph 5.
- Cordis is without sufficient information to form a belief as to the truth of the 6. allegations of paragraph 6 and therefore denies the allegations in paragraph 6.
- Cordis admits that Cordis advised Plaintiff that it had no interest in his product. 7. Cordis denies that this lack of interest in Plaintiff's "Product" was limited to a particular time or time period.
 - 8. Cordis denies the allegations of paragraph 8.
- Cordis is without sufficient information to form a belief as to the truth of the 9. allegations of paragraph 9 regarding Plaintiff's knowledge or state of mind and therefore denies

such allegations in paragraph 9. To the extent that paragraph 9 alleges any wrongdoing by Cordis, Cordis denies such allegations of paragraph 9.

- Cordis denies the allegations of paragraph 10.
- 11. Cordis admits that on or about March 2, 2001, Cordis received a letter from Plaintiff's counsel concerning the issues giving rise to the instant litigation. Cordis denies the allegations set forth in the substance of that letter.
- 12. Cordis is without sufficient information to form a belief as to the truth of the allegations of paragraph 12 and therefore denies the allegations in paragraph 12.
- 13. Cordis reasserts its responses to the allegations contained in paragraphs 1 through 12 of the Complaint as if fully set forth herein.
 - Cordis denies the allegations of paragraph 14.
 - 15. Cordis denies the allegations of paragraph 15.
- 16. Cordis reasserts its responses to the allegations contained in paragraphs 1 through15 of the Complaint as if fully set forth herein.
 - 17. Cordis denies the allegations of paragraph 17.
 - 18. Cordis denies the allegations of paragraph 18.
- 19. Cordis reasserts its responses to the allegations contained in paragraphs 1 through18 of the Complaint as if fully set froth herein.
 - Cordis denies the allegation in paragraph 20.
 - 21. Cordis denies the allegations of paragraph 21.

- 22. Cordis denies the allegations of paragraph 22.
- 23. Cordis denies that Plaintiff is entitled to any of the relief sought in the Complaint.

AFFIRMATIVE AND OTHER DEFENSES

Cordis states the following defenses without assuming the burden of proof as to any issue that otherwise would rest upon Plaintiff.

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

Plaintiff's claims are barred, in whole or in part, by laches.

Third Defense

Plaintiff's claims are barred, in whole or in part, by the equitable doctrine of estoppel.

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by waiver.

Fifth Defense

Plaintiff has failed to mitigate his damages, if any.

Sixth Defense

Plaintiff's requested relief, if any should be awarded, is limited to an amount of damages no greater than a fair, reasonable and nondiscriminatory license amount.

Of Counsel;

Kathryn A. Meisel JOHNSON & JOHNSON One Johnson & Johnson Plaza New Brunswick, NJ 08935

Dated: January 21, 2002

Douglas M. Campbell (Tenn. BPR #5634)
Campbell & Campbell
Suite 1200 James Building
735 Broad Street
Chattanooga, Tennessee 37402-1835

Chattanooga, Tennessee 37402-1835 (423) 266-1108

Richard A. Ripley LaTisha S. Gotell HOWREY SIMON ARNOLD & WHITE, LLP 1299 Pennsylvania Avenue, N.W. Washington, D.C. 20004 (202) 783-0800

Attorneys for CORDIS CORPORATION

CERTIFICATE OF SERVICE

I hereby certify that a copy of Defendant Cordis Corporation's Answer to the Complaint filed by Alexander A. Stratienko, M.D. has been served upon all counsel of record listed below by placing same in the U.S. Mail, properly addressed and postage prepaid, this 21th day of January, 2002.

John P. Konvalinka
Mathew D. Brownfield
GRANT, KONVALINKA & HARRISON, PC
633 Chestnut Street, Suite 900
Chattanooga, TN 37450-0900
Counsel for Plaintiff - Alexander A. Stratienko, M.D.

Douglas M Campbell, Esq.

FILED

JAN ZI 1 30 PM °02 SUPPLEMENTAL CIVIL COVER SHEET FOR CASES REMOVED FROM STATE COURT ILS. BECAUSE GOOGLE CASTERN DIST LEAR.

This form must be attached to the civil cover sheet at the time the case is filed in the PP. OI ENK United States District Court Clerk's Office

Additional sheets may be used as necessary

1.	Style of Case: Contract	
	please list the attorney(s) of record (but only	Intervenor(s), Counter-claimant(s), Cross- It temaining in the case and indicate their party type. Also, value actually made an appearance in the case) tame, correct mailing address, and phone number (including
	Party and Party Type	Attorney(s)
	Alexander A. Stratienko, MD (Plaintiff)	Grant Konvalinka & Harrison PC 633 Chestnut Street, Ste. 900 Chattanooga, TN 37450-0900
	Cordis Corporation (Defendant)	Campbell & Campbell 735 Broad Street Chattanooga, TN 37402-1835
2,	Jury Demand: Was a jury demand inade in state court?	Howrey Simon Arnold & White, LLP 1299 Pennsylvania Ave., NW, Washington, DC No 20004-2402
	If "Yes," by which party and on wh	at date?
	Plaintiff Porty	November 21, 2001 Date
3:	Answer;	
	Was an answer filed in state court?	Yes x No
		nt date? You must provide copies of all filed answers with the
	Party	Date

4	Inversed	Tt

The following parties have not been served at the time this case was removed:

Party

Reason(s) for No Service

N/A

5. Non-suited, Dismissed or Terminated Parties:

Please indicate any changes from the style on the state court complaint and papers and the reason for that change:

Party

Reason

N/A

EXHIBIT 16

IN THE CIRCUIT COURT FOR THE 11TH JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

CASE NO: 05-22711 CA22

RICHARD TIETJEN.

Plaintiff,

CORDIS CORPORATION. a Florida Corporation,

Defenda.	n	ŀ
U Cronua.	ΙF	L

CORDIS CORPORATION'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendant, Cordis Corporation ("Cordis") answers Plaintiff's Complaint ("the Complaint") as follows. Any allegation contained in the Complaint not expressly and specifically admitted by Cordis is hereby denied.

- Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint.
- 2. Cordis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint.
- In response to Paragraph 3 of the Complaint, Cordis admits that it is a Florida corporation with its principal place of business in Miami Lakes, Florida.
- In response to Paragraph 4 of the Complaint, Cordis admits that it designed, manufactured, marketed, distributed and sold the Cypher® Sirolimus-Eluting Coronary Stent ("Cypher® Stent") for use by physicians pursuant to the Premarket

Approval granted by the Federal Food and Drug Administration ("FDA"). Cordis denies the remaining allegations in Paragraph 4.

FACTUAL ALLEGATIONS

COMMON TO ALL COUNTS

- In response to Paragraph 5 of the Complaint, Cordis admits that it 5. designed, manufactured, marketed, distributed and sold the Cypher® Stent for use by physicians pursuant to the Premarket Approval granted by the FDA. Cordis admits that bare-metal stents are an alternative to the Cypher® Stent. Cordis denies the remaining allegations in Paragraph 5.
- In response to Paragraph 6 of the Complaint, Cordis admits that the 6. Cypher® Stent combines a metal stent with a medication called sirolimus. Cordis further admits that the Cypher® Stent has a polymer coating that contains the sirolimus medication. Finally, Cordis admits that the Cypher® Stent is different from bare-metal stents. Cordis denies the remaining allegations in Paragraph 6.
- 7. In response to Paragraph 7 of the Complaint, Cordis admits that it submitted a Premarket Approval application prior to marketing the Cypher® Stent.
- In response to Paragraph 8 of the Complaint, Cordis admits that on April 8. 24, 2003, the FDA approved the Cypher® Stent for angioplasty procedures to open clogged coronary arteries.
- 9. In response to Paragraph 9 of the Complaint, Cordis admits that it agreed with the FDA that after the Cypher® Stent was approved, Cordis would collect information on certain patients that received Cypher® Stents. Cordis denies the remaining allegations in Paragraph 9.

- In response to Paragraph 10 of the Complaint, Cordis admits that it marketed the Cypher® Stent for use by physicians pursuant to the Premarket Approval granted by the FDA. Upon information and belief, Cordis further admits that in October 2003, the FDA reported that more than 450,000 units had been distributed worldwide (more than 260,000 in the U.S. and more than 180,000 outside the U.S.). Cordis denies the remaining allegations in Paragraph 10.
- In response to Paragraph 11 of the Complaint, Cordis admits that the Cypher® Stent is a safe and effective treatment for certain cardiac conditions as determined by the patient's treating physician. Cordis further admits that it marketed and distributed the Cypher® Stent for use by physicians pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 11.
- In response to Paragraph 12 of the Complaint, upon information and belief, Cordis admits that the FDA reported by July 8, 2003, the FDA had received 47 Medical Device Reports ("MDRs") of stent thrombosis occurring at the time of implantation or within a few days of implantation.
- In response to Paragraph 13 of the Complaint, upon information and 13. belief, Cordis admits that the FDA reported on October 20, 2003 that the FDA received the medical device reports as set forth in paragraph 13 of the Complaint. Cordis affirmatively states that the FDA also reported on October 29, 2003 that it was still analyzing the information in these reports, and that the FDA did not have sufficient data to establish rates for these events, or to determine whether these rates were different from those experienced with bare metal stents. Cordis further states that on October

18, 2004, the FDA concluded that the Cypher® Stent, when implanted in accordance with the approved indications for use, is not associated with an excess of subacute thrombosis (SATs) compared to bare-metal stents, and that the reported rate of SATs is within the expected rate for any stent. Cordis denies the remaining allegations in paragraph 13 of the Complaint.

- Cordis denies the allegations in Paragraphs 14 of the Complaint. 14.
- Cordis denies the allegations in Paragraphs 15 of the Complaint. 15.
- Cordis lacks sufficient knowledge or information so as to form a belief as 16. to the truth of the allegations stated in Paragraph 16 of the Complaint.
- In response to Paragraph 17 of the Complaint, Cordis admits that it marketed and distributed the Cypher® Stent for use by physicians pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the allegations in Paragraph 17 of the Complaint.
- In response to Paragraph 18 of the Complaint, Cordis admits that it 18. marketed and distributed the Cypher® Stent for use by physicians pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the allegations in Paragraph 18 of the Complaint.
- Cordis lacks sufficient knowledge or information so as to form a belief as 19. to the truth of the allegations stated in Paragraph 19 of the Complaint.
- Cordis lacks sufficient knowledge or information so as to form a belief as 20. to the truth of the allegations stated in Paragraph 20 of the Complaint.
 - 21. Cordis denies the allegations in Paragraph 21 of the Plaintiff's Complaint.
 - Cordis denies the allegations in Paragraph 22 of the Plaintiff's Complaint. 22.

- 23. Cordis denies the allegations in Paragraph 23 of the Plaintiff's Complaint.
- 24. Cordis denies the allegations in Paragraph 24 of the Plaintiff's Complaint.

COUNT ONE

STRICT LIABILITY IN TORT

- In response to Paragraph 25 of the Complaint, Cordis admits that it is the 25. manufacturer of the Cypher® Stent and it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegation stated in Paragraph 25 that the Cypher® Stent was "implanted into Plaintiff." Cordis denies the remaining allegations in Paragraph 25.
 - Cordis denies the allegations stated in Paragraph 26 of the Complaint. 26.
 - Cordis denies the allegations stated in Paragraph 27 of the Complaint. 27.
 - Cordis denies the allegations stated in Paragraph 28 of the Complaint. 28.
 - Cordis denies the allegations stated in Paragraph 29 of the Complaint. 29.
 - Cordis denies the allegations stated in Paragraph 30 of the Complaint. 30.
 - 31. Cordis denies the allegations stated in Paragraph 31 of the Complaint.
 - Cordis denies the allegations stated in Paragraph 32 of the Complaint. 32.

COUNT TWO

NEGLIGENCE

- 33. The allegations in Paragraph 33 of the Complaint state a conclusion of law to which no response is required. To the extent a response is required, Cordis states that it complied with all legal duties.
 - Cordis denies the allegations in Paragraph 34 of the Complaint. 34.

- 35. Cordis denies the allegations in Paragraph 35 of the Complaint.
- 36. Cordis denies the allegations in Paragraph 36 of the Complaint,
- 37. Cordis denies the allegations in Paragraph 37 of the Complaint.
- 38. Cordis denies the allegations in Paragraph 38 of the Complaint.

COUNT THREE

BREACH OF IMPLIED WARRANTY

- In response to Paragraph 39 of the Complaint, Cordis admits that it 39. designed and manufactured the Cypher® Stent and it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. The remaining allegations in Paragraph 39 of the Complaint state conclusions of law to which a response is not required. To the extent a response is required, Cordis states that it complied with all legal duties.
- 40. Cordis lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations stated in Paragraph 40 of the Complaint.
- The allegations in Paragraph 41 of the Complaint state conclusions of law 41. to which a response is not required. To the extent a response is required, Cordis denies the allegations contained in Paragraph 41 of the Complaint.
 - 42. Cordis denies the allegations in Paragraph 42 of the Complaint.

COUNT FOUR

BREACH OF EXPRESS WARRANTY

In response to Paragraph 43 of the Complaint, Cordis admits that it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 43.

- In response to Paragraph 44 of the Complaint, Cordis admits that it marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 44.
- In response to Paragraph 45 of the Complaint, Cordis admits that it 45. marketed and distributed the Cypher® Stent pursuant to the terms of the Premarket Approval granted by the FDA. Cordis denies the remaining allegations in Paragraph 45.
- Cordis denies the allegations in Paragraph 46 of the Plaintiff's Complaint. 46. In response to the unnumbered paragraph following Paragraph 46, beginning "WHEREFORE," Cordis denies the allegations contained in that paragraph.

<u>AFFIRMATIVE DEFENSES</u>

FIRST AFFIRMATIVE DEFENSE

The claims asserted against Cordis are preempted either in whole or in part by the Federal Food, Drug & Cosmetic Act, the Medical Device Amendments thereto and/or any regulations promulgated thereunder, and the Supremacy Clause of Article VI of the United States Constitution and/or by the doctrine of deference to agency expertise.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

THIRD AFFIRMATIVE DEFENSE

The claims asserted in the Complaint are barred, in whole or in part, by the applicable statute of limitations or statute of repose, and the doctrines of estoppel, waiver, laches, and unclean hands.

FOURTH AFFIRMATIVE DEFENSE

Cordis did not make to Plaintiff nor did Cordis breach any express or implied warranties and/or breach any warranties created by law. To the extent Plaintiff relies on any theory of breach of warranty, any such claims are barred based upon Plaintiff's lack of privity with Cordis and, additionally, because there was no reliance upon any warranties, if any, of Cordis.

FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff relies on any theory of breach of warranty, any such claims are barred in that Plaintiff failed to provide Cordis with timely notice of any alleged breach of warranty. Cordis asserts each and every defense and presumption available under the Uniform Commercial Code existing and which may arise in the future, as enacted in the State of Florida, and any other state whose law is deemed to apply in this case.

SIXTH AFFIRMATIVE DEFENSE

Cordis affirmatively states that Plaintiff had full knowledge of the risks and possible adverse consequences pertaining to the medical treatment received and all or part of the injuries, damages and/or losses sustained by Plaintiff, if any, arose from, and were caused by, risks of which Plaintiff were so aware, and such risks were accepted and assumed by Plaintiff, and for that reason, any recovery against Cordis should be diminished, reduced, offset or barred, in accordance with the principles of informed consent.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff sustained any of the injuries alleged in the Complaint, which Cordis denies, there was an intervening and/or superseding cause or causes leading to such alleged injuries and, as such, any action or omission on the part of Cordis was not a proximate cause of Plaintiff's alleged injuries.

EIGHTH AFFIRMATIVE DEFENSE

If Plaintiff sustained the injuries or incurred the expenses alleged in the Complaint, which Cordis denies, such injuries and/or expenses resulted from preexisting and/or unrelated medical, genetic and/or idiosyncratic conditions, diseases, or illness of Plaintiff.

NINTH AFFIRMATIVE DEFENSE

Cordis states that any and all causes of action maintained by Plaintiff against it based upon any alleged defect in its product are barred by the "learned intermediary" doctrine, or the "informed intermediary" doctrine, and/or the principles of §388 of the Restatement (Second) of Torts.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because the methods, standards, and techniques utilized by Cordis in designing and manufacturing the product in question and in issuing warnings and instructions with respect to its use were in conformity with the generally recognized, reasonably available, and reliable state of knowledge in the field at the time the product was manufactured.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under the Restatement (Second) of Torts: Product Liability §402A and comments thereto and/or the Restatement (Third) of Torts: Products Liability §6 and comments thereto.

TWELFTH AFFIRMATIVE DEFENSE

Cordis was not under any legal obligation to give the Plaintiff notice or warnings about the use of Cypher® Stent. All notices or warnings were properly given to physicians, the only persons authorized by law to prescribe the Cypher® Stent.

THIRTEENTH AFFIRMATIVE DEFENSE

The conduct of Cordis and the Cypher® Stent conformed to the state of the art at all relevant times.

FOURTEENTH AFFIRMATIVE DEFENSE

The Cypher® Stent was intended for and was sold to a knowledgeable and sophisticated user over whom Cordis had no control and who was fully informed of the risk and dangers, if any, associated with the Cypher® Stent and the precautions, if any, required to avoid those risks and dangers.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs alleged injuries and damages were caused or contributed, directly and proximately, in whole or in part, by the negligence, fault, acts, breaches, omissions, or other wrongful conduct of Plaintiff, or others that are attributable to him, so that any recovery by Plaintiff must be diminished by the degree such conduct is attributed to Plaintiff in accordance with applicable law.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries and damages were caused or contributed, directly and proximately, in whole or in part, by the negligence, fault, acts, breaches, omissions or other wrongful conduct of others so that any damages awarded in favor of Plaintiff are subject to the comparative fault provisions of section 768.81, Florida Statutes, and Cordis cannot be liable for more than its proportionate share of any non-economic damages awarded. Further, pursuant to Fabre v. Marin, 623 So. 2d 1182 (Fla. 1993), any damages awarded to the Plaintiff are subject to apportionment by the jury of the total fault of all participants.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff failed to exercise reasonable care and diligence to mitigate the injuries and damages, if any, alleged in the Complaint, so that any recovery by Plaintiff must be apportioned in direct proportion to such failure to mitigate in accordance with applicable laws.

EIGHTEENTH AFFIRMATIVE DEFENSE

Should Cordis be held liable to Plaintiff, which liability is specifically denied, Cordis is entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor for the same injuries alleged in the Complaint.

NINETEENTH AFFIRMATIVE DEFENSE

Should Cordis be held liable to Plaintiff, which liability is specifically denied, Cordis is entitled to a set-off for the total of all amounts paid to Plaintiff from any collateral sources.

TWENTIETH AFFIRMATIVE DEFENSE

The Complaint should be dismissed on the grounds of forum non conveniens.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Cordis reserves the right to assert other such defenses as may become available or appear during discovery proceedings in this case and hereby reserves the right to amend its answer to assert any such defenses.

WHEREFORE, Cordis respectfully requests that the Plaintiff's Complaint be dismissed with prejudice at Plaintiff's cost, that Cordis be awarded its costs and expenses, including reasonable attorneys' fees to the extent permitted by law, and for such further relief as this Court deems just and equitable.

> Jeffrey B. Shapiro Fla. Bar No. 484113 Neville M. Leslie Fla. Bar No. 0107492 Arnstein & Lehr LLP

Attorneys for Cordis Corporation Suite 400, 201 S. Biscayne Blvd.

Miami, Florida 33131

Telephone: (305) 374-3330 Facsimile: (305) 374-4744

E-Mail:

ibshapiro@arnstein.com

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing was sent via U.S. Mail on the 124 day of December, 2005, to Alan D. Sackrin, Law Office of Alan D. Sackrin, 2100 East Hallandale Beach Blvd., Suite 200, Hallandale Beach, Florida 33009.

> Jeffrey B. Shapiro Fla. Bar No. 484113 Neville M. Leslie Fla. Bar No. 0107492 Arnstein & Lehr LLP

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Miami, Florida 33131

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Facsimile: E-Mail:

jbshapiro@arnstein.com

82419

EXHIBIT 17

IN THE CIRCUIT COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

VICKIE CLAY-TAYLOR, INDIVIDUALLY AND ON BEHALF OF THE WRONGFUL DEATH BENEFICIARIES OF WASH CLAY, JR., DECEASED

PLAINTIFF

VS.

CIVIL ACTION NO. 251-04-988 CIV

JAMES CLAY HAYS, M.D.; DAVID H. MULHOLLAND, M.D.; DOMINIC JAEGER, M.D.; ST. DOMINIC-JACKSON MEMORIAL HOSPITAL; CORDIS CORPORATION; JOHNSON AND JOHNSON; AND, JOHN AND JANE DOES 1-5

DEFENDANTS

ANSWER AND AFFIRMATIVE DEFENSES OF JOHNSON & JOHNSON AND CORDIS CORPORATION

Defendants Johnson & Johnson and Cordis Corporation ("J&J and Cordis") present the following Answer and Affirmative Defenses to the Complaint:

FIRST DEFENSE

The Complaint fails to state a claim against either J&J or Cordis upon which relief can be granted.

SECOND DEFENSE

J&J is not a proper party defendant to this action. The medical device at issue in this case, a Cypher Sirolimus-Eluting Coronary Stent, is a product of Cordis. Although Cordis is a wholly owned subsidiary of J&J, it is a separate corporate entity. J&J did not manufacture, market, sell or distribute a Cypher Sirolimus-Eluting Coronary Stent. Accordingly, it has no liability to plaintiff.

THIRD DEFENSE - ANSWER

J&J and Cordis answer the Complaint, paragraph by paragraph, as follows:

I. <u>INTRODUCTION</u>

J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in the "Introduction" section of the Complaint and, therefore, deny same.

II. PARTIES

- J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint and, therefore, deny same.
- 2. The allegations contained in paragraph 2 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, therefore, deny same.
- 3. The allegations contained in paragraph 3 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint and, therefore, deny same.
- 4. The allegations contained in paragraph 4 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint and, therefore, deny same.
- 5. The allegations contained in paragraph 5 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint and, therefore, deny same.

- 6. Cordis admits that it is a wholly owned subsidiary of J&J, that it is a foreign corporation with its principal place of business in the State of Florida, and that it has accepted service of process in this action. Except as expressly admitted herein, Cordis denies the remaining allegations contained in paragraph 6 of the Complaint.
- 7. J&J admits that it is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, and admits that it has accepted service of process in this action. Except as expressly admitted herein, J&J denies the remaining allegations contained in paragraph 7 of the Complaint.
- 8. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint and, therefore, deny same.

III. JURISDICTION AND VENUE

- 9. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and, therefore, deny same.
- 10. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and, therefore, deny same.

IV. FACTS

- 11. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint and, therefore, deny same.
- 12. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint and, therefore, deny same.
- 13. Except as hereinafter expressly admitted, J&J and Cordis deny the allegations contained in paragraph 13 of the Complaint. J&J and Cordis admit that in October and November of 2003, the FDA issued "Talk Papers" regarding new information to be considered prior to the use

of the Cypher Sirolimus-Eluting Coronary Stent. The "Talk Papers" speak for themselves as to their terms.

- 14. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint and, therefore, deny same.
- 15. J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Complaint and, therefore, deny same.
 - 16. J&J and Cordis deny the allegations contained in paragraph 16 of the Complaint,

V. CLAIMS FOR RELIEF AGAINST DEFENDANTS ST. DOMINIC-JACKSON MEMORIAL HOSPITAL, JAMES CLAY HAYS, M.D.; DAVID H. MULHOLLAND, M.D.; DOMINIC JAEGER, M.D.; AND JOHN AND JANE DOES 1-5

- 17. J&J and Cordis incorporate by reference all of the paragraphs of the Answer as if fully set forth herein.
- 18. The allegations contained in paragraph 18 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint and, therefore, deny same.
- 19. The allegations contained in paragraph 19 of the Complaint are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the Complaint and, therefore, deny same.
- 20. The allegations contained in paragraph 20 of the Complaint, including subparagraphs (a) through (h), are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to

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form a belief as to the truth of the allegations contained in paragraph 20 of the Complaint, including subparagraphs (a) through (h), and, therefore, deny same.

- The allegations contained in paragraph 21 of the Complaint are not directed to J&J 21. and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of the Complaint and, therefore, deny same.
- The allegations contained in paragraph 22 of the Complaint are not directed to J&J 22. and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint and, therefore, deny same.
- The allegations contained in paragraph 23 of the Complaint, including 23. subparagraphs (a) through (h), are not directed to J&J and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint and, therefore, deny same.
- The allegations contained in paragraph 24 of the Complaint are not directed to J&J 24. and Cordis and no response is required. To the extent a response is required, J&J and Cordis lack information and knowledge sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the Complaint and, therefore, deny same.

CLAIMS FOR RELIEF AGAINST DEFENDANTS CORDIS CORPORATION AND JOHNSON AND JOHNSON

J&J and Cordis incorporate by reference all of the paragraphs of the Answer as if 25. fully set forth herein.

- 26. Except as hereinafter expressly admitted, J&J and Cordis deny the allegations contained in paragraph 26 of the Complaint, including subparagraphs (a) through (n). J&J and Cordis admit that Cordis designs, manufactures and sells a Cypher Sirolimus-Eluting Coronary Stent and that the Cypher Sirolimus-Eluting Coronary Stent was approved for sale in the United States in April 2003. Subsequently in October and November of 2003, the FDA issued "Talk Papers" regarding new information to be considered by physicians prior to the use of the Cypher Sirolimus-Eluting Coronary Stent. The duties, if any, imposed upon these defendants by law constitute legal conclusions requiring no response, but defendants deny that they breached any such duties.
 - 27. J&J and Cordis deny the allegations contained in paragraph 27 of the Complaint.
 - 28. J&J and Cordis deny the allegations contained in paragraph 28 of the Complaint.
 - 29. J&J and Cordis deny the allegations contained in paragraph 29 of the Complaint.

VII. DAMAGES

- 30. J&J and Cordis incorporate by reference all of the paragraphs of the Answer as if fully set forth herein.
- 31. J&J and Cordis deny the allegations contained in paragraph 31 of the Complaint, including subparagraphs (a) through (h).
 - 32. J&J and Cordis deny the allegations contained in paragraph 32 of the Complaint.
 - 33. J&J and Cordis deny the allegations contained in paragraph 33 of the Complaint.

VIII. RELIEF DEMANDED

J&J and Cordis deny the allegations contained in paragraph beginning with the word "WHEREFORE" and further deny that Plaintiff is entitled to any recovery whatsoever from J&J and Cordis.

FOURTH DEFENSE

At all times material hereto, the Cypher Sirolimus-Eluting Coronary Stent conformed to the state-of-the-art and was not unreasonably dangerous or defective.

FIFTH DEFENSE

To the extent that Wash Clay, Jr.'s reactions to the Cypher Sirolimus-Eluting Coronary Stent were idiosyncratic reactions, J&J and Cordis deny any liability.

SIXTH DEFENSE

The injuries to Wash Clay, Jr., if any, were caused in whole or in part by the acts or omissions of others for whose conduct J&J and Cordis are not responsible. The injuries to Wash Clay, Jr., if any, were not caused by any acts or omissions of J&J or Cordis.

SEVENTH DEFENSE

The injuries to Wash Clay, Jr., if any, were the result of intervening or superseding causes over which J&J and Cordis had no control.

EIGHTH DEFENSE

The Cypher Sirolimus-Eluting Coronary Stent was intended for and sold to a knowledgeable and sophisticated user over whom J&J and Cordis had no control and who was fully informed of the risks and dangers, if any, associated with the medical device and the precautions, if any, required to avoid those risks and dangers.

NINTH DEFENSE

The injuries to Wash Clay, Jr., if any, were the result of pre-existing or subsequent conditions unrelated to the Cypher Sirolimus-Eluting Coronary Stent.

TENTH DEFENSE

The injuries to Wash Clay, Jr., if any, were the result of misuse of the Cypher Sirolimus-Eluting Coronary Stent.

ELEVENTH DEFENSE

If J&J and Cordis are found to have made any warranties alleged by Plaintiff (which J&J and Cordis specifically deny), Plaintiff's claims for breach of warranty, both expressed and/or implied, are barred by their failure to give notice as required by Miss. Code Ann. § 75-2-607 (1972).

TWELFTH DEFENSE

Some or all of the damages alleged by Plaintiff are barred by Miss. Code Ann. § 75-2-714, 715 (1972).

THIRTEENTH DEFENSE

J&J and Cordis affirmatively plead the application of Comment k to the Restatement of Torts (Second) Section 402A and Restatement (Third) Torts: Products Liability Section 6. Cordis provided adequate and complete warnings to Wash Clay, Jr.'s prescribing physicians and, therefore, the product was not defective or unreasonably dangerous.

FOURTEENTH DEFENSE

Cordis provided adequate and complete warnings of all risks associated with the subject stent to the medical professionals. Because Cordis adequately warned Wash Clay, Jr.'s physicians of the risks associated with the medical device, the learned intermediary doctrine bars any recovery.

FIFTEENTH DEFENSE

The applicable statute of limitations and/or the doctrine of laches bar Plaintiff's claims.

SIXTEENTH DEFENSE

J&J and Cordis affirmatively plead Miss. Code Ann. § 85-5-7 (1972).

SEVENTEENTH DEFENSE

To the extent that Plaintiff's claims are based upon any theory of product liability, they are barred or limited by Mississippi's Product Liability Act, Miss. Code Ann. § 11-1-63 (1972).

EIGHTEENTH DEFENSE

Wash Clay, Jr. knew or should have known of any risk associated with the Cypher Sirolimus-Eluting Coronary Stent; therefore, the doctrine of assumption of the risk may bar or diminish any recovery.

NINETEENTH DEFENSE

Plaintiff failed to mitigate any alleged damages.

TWENTIETH DEFENSE

Plaintiff's claims are barred because J&J and Cordis complied with the applicable statutes and with the requirements and regulations of the Food and Drug Administration.

TWENTY-FIRST DEFENSE

The United States Food and Drug Administration ("FDA") regulates medical devices, including the Cypher Sirolimus-Eluting Coronary Stent, and has approved the medical device, as well as the accompanying labeling, as safe and effective. Accordingly, Plaintiff's claims, predicated on state tort law and alleging the subject stent to be unsafe, conflict with the FDA's safety decisions and are pre-empted by the Supremacy Clause of the United States Constitution, the Food, Drug and Cosmetic Act, and the Medical Device Amendments of 1976, 21 U.S.C. Section 360 et seq.

TWENTY-SECOND DEFENSE

Plaintiff's claims for punitive damages cannot be sustained because due process requires that the standard of liability for determining whether punitive damages are warranted requires that defendants have participated in intentionally malicious conduct or have actual knowledge of malicious conduct, and Mississippi law does not provide such an instruction in violation of J&J's and Cordis' due process rights guaranteed by the Fourteenth Amendment of the United States Constitution and Article 3, Section 14 of the Constitution of the State of Mississippi.

TWENTY-THIRD DEFENSE

Plaintiff's claims for punitive damages cannot be sustained because Mississippi law permits the application of joint and several liability for punitive damages, which violates J&J's and Cordis' due process and equal protection rights guaranteed by the Fourteenth Amendment of the United States Constitution and Article 3, Section 14 of the Constitution of the State of Mississippi.

TWENTY-FOURTH DEFENSE

To the extent Plaintiff seeks punitive damages, these sanctions must be limited by J&J's and Cordis' relevant economic activity in the State of Mississippi.

TWENTY-FIFTH DEFENSE

J&J and Cordis affirmatively plead all applicable protections and defenses available to them under the Mississippi Tort Reform Bills.

TWENTY-SIXTH DEFENSE

J&J and Cordis reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

WHEREFORE, PREMISES CONSIDERED, Johnson & Johnson and Cordis Corporation demand that the Complaint against them be dismissed with prejudice with all costs taxed to Plaintiff.

DATED this the 27th day of December, 2004.

Respectfully submitted,

CHRISTY D. JONES (MB No. 3192) CHAD R. HUTCHINSON (MB No. 100432)

ATTORNEYS FOR JOHNSON & JOHNSON AND CORDIS CORPORATION

OF COUNSEL:

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC 17th Floor, Amsouth Plaza Post Office Box 22567 Jackson, MS 39225-2567 Tel: (601) 948-5711 Fax: (601) 985-4500 Page 60 of 123

CERTIFICATE OF SERVICE

I, Chad R. Hutchinson, one of the attorneys for Johnson & Johnson and Cordis Corporation, do hereby certify that I have this day served a true and correct copy of the above and foregoing Answer and Affirmative Defenses of Johnson & Johnson and Cordis Corporation by mailing same via United States Mail, postage fully prepaid thereon, to the following:

> Dale Danks, Jr., Esq. Danks, Dye, Mills and Pittman Post Office Box 2178 Jackson, Mississippi 39225-2178

Pieter Teeuwissen, Esq. Post Office Box 16787 Jackson, Mississippi 39236

ATTORNEYS FOR PLAINTIFF

So certified, this the 27th day of December, 2004.

Chade Hutlungn CHAD R. HUTCHINSON

JACKSON 990839v1

EXHIBIT 18

IN THE CIRCUIT COURT OF THE 11th JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

CASE NO. 04-18851 CA 13

EUGENIA PARIS and LUIS QUIROS, her husband,

Plaintiffs,

v.

CORDIS CORPORATION,

Defendant(s).

DEFENDANT'S ANSWER AND AFFIRMATIVE DEFENSES

Defendant, CORDIS CORPORATION ("CORDIS"), by and through its undersigned counsel, hereby serves the following Answer and Affirmative Defenses to Plaintiffs' Complaint and states:

GENERAL ALLEGATIONS

- 1. Without knowledge, therefore denied.
- 2. It is admitted that Cordis is a Florida corporation with its principal place of business in the State of Florida, Cordis has no knowledge of the other allegations of this paragraph and the same are therefore denied.
 - 3. Admitted.
 - Without knowledge, therefore denied.
 - 5. Without knowledge, therefore denied.
 - 6. Without knowledge, therefore denied.
 - 7. Without knowledge, therefore denied.

THORNTON, DAVIS & FEIN, P.A., ATTORNEYS AT LAW

CWY000800A

CASE NO. 04-16-51 CA 13

- 8. Without knowledge, therefore denied.
- 9. Without knowledge, therefore denied.
- 10. Without knowledge, therefore denied.
- 11. Without knowledge, therefore denied.
- 12. Without knowledge, therefore denied.
- 13. Without knowledge, therefore denied.
- 14. Without knowledge, therefore denied.
- 15. Without knowledge, therefore denied.
- 16. Without knowledge, therefore denied.
- 17. Without knowledge, therefore denied.
- 18. Without knowledge, therefore denied.
- 19. Without knowledge, therefore denied.
- 20. Without knowledge, therefore denied.
- 21. Without knowledge, therefore denied.
- 22. Without knowledge, therefore denied.
- 23. Without knowledge, therefore denied.
- 24. Without knowledge, therefore denied.
- 25. Without knowledge, therefore denied.
- 26. Without knowledge, therefore denied.
- 27. Without knowledge, therefore denied.
- 28. Denied.
- 29. Denied.
- 30. Without knowledge, therefore denied.
- 31. Without knowledge, therefore denied.



CASE NO. 04-10051 CA 13

COUNT I - CLAIM FOR NEGLIGENCE CORDIS

- 32. CORDIS realleges and reavers its responses to the allegations contained in the General Allegation above, and all other necessary allegations.
 - 33. Denied.
 - 34. Denied.
 - a). Denied.
 - b). Denied.
 - Denied. c).
 - d). Denied.
 - 35. Denied.
 - 1. Denied.
 - 2. Denied.
 - 3. Denied.
 - 4. Denied.
 - 36. Denied.

COUNT II - CLAIM FOR BREACH OF IMPLIED WARRANTIES AGAINST COOK

- 37. CORDIS realleges and reavers its responses to the allegations contained in the General Allegations above and all other necessary allegations.
 - 38. Denied.
 - 39. Denied.
 - 40. Denied.
 - 41. Denied.
 - 1. Denied.
 - 2. Denied.

- 3. Denied.
- 4. Denied.
- 42. Denied.

COUNT III - CLAIM FOR STRICT LIABILITY IN TORT AGAINST COOK

- CORDIS realleges and reavers its responses to the allegations contained in the 43. General Allegations above and all other necessary allegations.
 - 44. Denied.
 - 45. Denied.
 - 46. Denied.
 - 47. Denied.
 - 48. Denied.
 - Denied. 1.
 - 2. Denied.
 - Denied. 3.
 - 4. Denied.
 - 49. Denied.

COUNT IV - CLAIM FOR THE PLAINTIFF, LUIS QUIROS

- 50. CORDIS realleges and reavers its responses to the allegations contained in the General Allegations above, and all other necessary allegations.
 - 51. Without knowledge, therefore denied.
 - 52. Denied.

CASE NO. 04-10051 CA 13

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

CORDIS asserts that Plaintiffs' Complaint should be dismissed based on forum 53 non conveniens. Foreign law, including, but not limited to, Costa Rican law will have to be applied to the issues involved in this action.

SECOND AFFIRMATIVE DEFENSE

CORDIS asserts that at all times material hereto, EUGENIA PARIS, was 54. negligent in her own conduct, such negligence being the sole or contributing cause of the damages alleged, thereby barring Plaintiff's recovery or in the alternative reducing said recovery proportionately.

THIRD AFFIRMATIVE DEFENSE

CORDIS assets that at all times material hereto, EUGENIA PARIS and/or LUIS 55. QUIROS, were negligent in their own conduct, such negligence being the sole or contributing cause of the damages alleged, thereby barring Plaintiffs' recovery or in the alternative reducing said recovery proportionately.

FOURTH AFFIRMATIVE DEFENSE

CORDIS asserts that the Plaintiffs' damages, if any, arising from the alleged 56. incident, are solely and proximately the result of the actions and/or negligence of other parties, persons, firms, or corporations over whom CORDIS has no control or duty to control, and for whose actions CORDIS cannot be held responsible or legally liable. Accordingly, if CORDIS is found to be liable, which liability CORDIS expressly denies, to Plaintiffs, any liability should be only for that portion of damages, if any, due to CORDIS's own fault, and not the fault of others, whether or not named in the present action, over whom CORDIS had no control, as provided by Florida Statute §768.81 and as interpreted by the Florida Supreme Court in Fabre v. Marin, 623

CASE NO. 04-1-651 CA 13

So. 2d 1182 (Fla. 1993). Pursuant to Nash v. Wells Fargo Guard Serv., 678 So. 2d 1262 (Fla. 1996), CORDIS identifies the following entities as non-party tortfeasors in this case: (1) Cima Hospital of San Jose, (2) Plaintiff's treating physician(s), (3) any and all doctors involved in the alleged procedure of inserting into Plaintiff, EUGENIA PARIS a Cordis Vena Cava Filter, and (4) other currently unidentified parties, persons, firms, or corporations over whom CORDIS had no control or duty to control, and for whose actions CORDIS cannot be held responsible or legally liable. CORDIS reserves the right to amend this affirmative defense to identify any such other individuals or entities as discovery proceeds.

FIFTH AFFIRMATIVE DEFENSE

57. CORDIS asserts that the subject incident was the result of misuse of the subject product, including, but not limited to, improper placement. The misuse was the sole proximate and/or contributing cause of any damages claimed by the Plaintiffs. Accordingly, the Plaintiffs are barred in whole or in part from any recovery.

SIXTH AFFIRMATIVE DEFENSE

If CORDIS is found liability to the Plaintiffs, which liability CORDIS expressly 58. denies, such liability must be reduced by collateral sources as provided by Florida Statute §768.76.

SEVENTH AFFIRMATIVE DEFENSE

If CORDIS is found liable to Plaintiffs, which liability CORDIS expressly denies, 59. then CORDIS is entitled to a set-off for all settlements/benefits received by Plaintiffs.

EIGHTH AFFIRMATIVE DEFENSE

CORDIS asserts that at some time subsequent to the time that the product left the 60. possession and control of CORDIS, it was materially altered and/or modified, such material alteration and/or modification being the sole proximate and/or contributing cause of any

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CASE NO. 04-10551 CA 13

injuries/damages claimed by Plaintiffs. Accordingly, Plaintiffs are thereby barred in whole or in part from any recovery against CORDIS.

NINTH AFFIRMATIVE DEFENSE

61. CORDIS provided warnings of the contraindications, precautions, and potential complications of the product at issue to some other person or persons, or those person or persons already had knowledge of such warnings, and CORDIS could reasonably rely upon such person or persons to communicate the warnings to the ultimate users of the product, thereby barring Plaintiffs' recovery from CORDIS. Therefore, CORDIS pleads the doctrine of the Learned Intermediary as an Affirmative Defense.

TENTH AFFIRMATIVE DEFENSE

62. Plaintiffs failed to mitigate their damages, if any.

ELEVENTH AFFIRMATIVE DEFENSE

63. The subject product allegedly manufactured by CORDIS, if in fact manufactured by CORDIS, was manufactured using state of the art engineering, design, manufacturing procedures, and materials when engineered, designed, and manufactured pursuant to Florida Statute §768.1257.

TWELFTH AFFIRMATIVE DEFENSE

64. CORDIS asserts that CORDIS complied with all relevant government rules, regulations, and standards with regard to the design, manufacture, testing, and inspection of the subject product, and as such, is entitled to a rebuttable presumption of non-liability pursuant to Florida Statutes §768.1256.

CASE NO. 04-15-51 CA 13

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the 65. use of the product at issue in this case and such assumption of the risk bars in whole or in part the damages Plaintiffs seek to recover herein.

FOURTEENTH AFFIRMATIVE DEFENSE

CORDIS asserts that the incident and damages alleged in the Plaintiffs' 66. Complaint were completely the result of intervening and unforeseeable causes for which CORDIS had no duty to protect the Plaintiffs.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are preempted in whole or in part by the federal Food, Drug and 67. Cosmetic Act, and the Supremacy Clause of Article VI of the United States Constitution.

SIXTEENTH AFFIRMATIVE DEFENSE

CORDIS asserts Plaintiffs' Complaint should be dismissed for failure to join 68. indispensable parties.

SEVENTEENTH AFFIRMATIVE DEFENSE

69. CORDIS asserts that Plaintiffs have failed to state a cause of action.

EIGHTEENTH AFFIRMATIVE DEFENSE

CORDIS reserves the right to raise any additional defenses which may be 70. discovered through participation in discovery in the case.

WHEREFORE, having fully responded to Plaintiffs' Complaint, Defendant, CORDIS CORPORATION, prays that judgment be entered in its favor and that it be awarded all taxable costs and such further relief as this Court deems just and proper.

Defendant, CORDIS CORPORATION, hereby demands a trial by jury in this cause.

CASE NO. 04-1351 CA 13

CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing was served by United States mail on October _______, 2004 to: Leo A. Manzanilla, Esq., Attorney for Plaintiff, 2600 Douglas Road, Suite 1108, Coral Gables, Florida 33134.

THORNTON, DAVIS & FEIN, P.A.

Attorneys for Defendant Brickell BayView Centre, Suite 2900 80 Southwest 8th Street Miami, Florida 33130

Tel: 305-446-2646

Fax: 305-441-2374

By:

Fla. Bar No. 294977 EDELBERTO FARRÉS Fla. Bar No. 0070793

EXHIBIT 19

EFiled: Jan 17 2007 11:2240 Transaction ID 13480359

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE IN AND FOR NEW CASTLE COUNTY

	
CORDIS CORPORATION, Plaintiff,)) Civil Action No. 2504-N)
v. WYETH and WYETH PHARMACEUTICALS DIVISION, Defendants.) REDACTED — PUBLIC VERSION) JANUARY 17, 2007)))

ANSWERING BRIEF IN OPPOSITION TO WYETH'S MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO STAY THIS ACTION

Of Counsel:

Gregory L. Diskant Michael J. Timmons Irena Royzman Patrick Almonrode PATTERSON BELKNAP WEBB & TYLER LLP 1133 Avenue of the Americas New York, NY 10036 (212) 336-2000

Lawrence C. Ashby (I.D. #468) Steven J. Balick (I.D. #2114) Richard L. Renck (LD. #3893) ASHBY & GEDDES 500 Delaware Avenue, 8th Floor Wilmington, DE 19899 (302) 654-1888

Attorneys for Plaintiff Cordis Corporation

Dated: January 11, 2007

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L INTRODUCTION

Cordis Corporation ("Cordis") submits this memorandum in opposition to Wyeth's motion to dismiss or stay this action (the "Court of Chancery Action") in favor of the suit Wyeth brought in Delaware District Court (the "Federal Court Action"). Clearing the rhetoric from Wyefh's brief reveals that its motion is based on this single point: Wyeth filed its complaint in Federal Court in the afternoon of October 26, 2006 and served the complaint in the morning of October 27, while Cordis filed its complaint in Court of Chancery in the afternoon of October 27.

Document 35-2

This chronology, according to Wyeth, compels this Court to dismiss or stay the Court of Chancery Action as second filed under the McWane doctrine, which allows a court to dismiss or stay an action if there is a prior pending action between the same parties in a court that is capable of resolving the parties' dispute. Wyeth's motion should fail for two reasons: (1) due to the circumstances surrounding Wyeth's filing and service of its complaint, Wyeth's Federal Court Action should not be accorded the status of a prior pending action, and (2) because it has no subject matter jurisdiction, the Federal Court is not capable of resolving this dispute. This Court can deny Wyeth's motion now for the first reason. Alternatively, it can await the federal court's resolution of the jurisdictional question before addressing the second reason.

REDACTED

in reality, the Federal Court

Action was filed as a bargaining chip by Wyeth for use in another dispute between the parties.

REDACTED In July 2006, Alza

Corporation ("Alza"), a sister company of Cordis, sued Wyeth in the Eastern District of Texas over Wyeth's infringement of Alza's U.S. Patent No. 6,440,457 to Edgren et al. (the "Edgren Patent").

Nevertheless, that afternoon Wyeth filed its complaint in Federal Court. The next morning, October 27, Wyeth refused to provide Cordis' attorneys with an unredacted version of the complaint unless Cordis agreed to accept service. On the afternoon of October 27, Cordis filed its complaint ("Cordis Complaint") in Court of Chancery. See Cordis Compl. Cordis has subsequently moved to dismiss or stay Wyeth's Federal Court Action. Exhibit 3.

Wyeth's race to the courthouse should not give it an advantage. Rather, under the circumstances, the two lawsuits should be considered as being contemporaneously filed, providing Wyeth's Federal Court Action with no advantage over Cordis' Court of Chancery Action. Once the cases are viewed on equal footing, it is clear that Court of Chancery is the appropriate court for the dispute to be resolved. It is undisputed that the Court of Chancery has jurisdiction and the required expertise in state contractual law. In contrast, as set forth in Cordis' federal court motion, because there is no subject matter jurisdiction in the Federal Court, that

court cannot resolve the dispute. In addition, because there is no federal legal issue in dispute, the Federal Court has no special expertise over the matter. Wyeth's motion should be denied.

11. FACTS

A. The Parties

Cordis is engaged in the business of developing, manufacturing and selling innovative medical devices. It is the world's leading developer and manufacturer of interventional cardiology, radiology and electrophysiology products for circulatory disease management. Cordis is a wholly owned subsidiary of Johnson & Johnson. Cordis is a Florida corporation with its principal place of business in Warren, New Jersey. Cordis Compl. at \$\infty\$6-7.

Wyeth states that it is a Delaware corporation with a principal place of business in Madison, New Jersey. Exhibit 4. Wyeth is engaged in the business of developing, manufacturing and selling pharmaceutical products. Cordis Compl. at ¶11. It does not compete with Cordis and, other than supplying Cordis with rapamycin under the Agreement, has no activity in interventional cardiology, radiology or electrophysiology products for circulatory discase management.

B.

REDACTED

Cordis' Cypher Stent C.

Cordis developed the first drug-eluting stent, the Cypher stent, using rapamycin provided by Wyeth. Cypher has been sold and used in Europe since 2002 and was approved in the United States in April 2003. Cordis Compl. at ¶16.

The Cypher stent has been an overwhelming commercial success. Since its introduction in Europe in 2002, over 3.5 million Cypher stents have been implanted. Sales have reached over \$8 billion. Exhibit 3 at 4; see also Anderson Declaration (Exhibit 16) at ¶19.

REDACTED

Alza's Lawsuit Against Wyeth D.

In late 2005 the Edgren dispute arose.

REDACTED

REDACTED

Wyeth sells over \$3 billion a year of Effexor. Exhibit 7 at p. 3. REDACTED

ż.

Alza

sued Wyeth in July 2006. Exhibit 8.

REDACTED

E.

REDACTED

REDACTED

F.

REDACTED

1,

REDACTED

2.

REDACTED

3,

REDACTED

G.

REDACTED

Wyeth filed a suit on the afternoon of October 26 in

the United States District Court for the District of Delaware.

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H. Wyeth's Federal Court Action

1. The Service of the Complaint in the Federal Court Action

On the morning of October 27, Cordis' attorneys went to the Federal Courthouse to obtain a copy of the complaint, but only a redacted version was available. Exhibit 13.

Cordis' attorneys then promptly contacted Wyeth's attorneys that morning, seeking an unreducted version of the complaint. Rather than extending the professional courtesy of providing Cordis' attorneys with a copy of the complaint, Wyeth's attorneys required that Cordis agree to accept service in order to obtain a copy of the full complaint. The full complaint was provided at 10 a.m., only after Cordis agreed to accept service. Exhibit 14.

2. The Complaint in the Federal Court Action

Wyeth's complaint in the Federal Court Action seeks "damages and declaratory and injunctive relief." Exhibit 4 at ¶ 1. REDACTED

REDACTED

Wyeth asserts that Cordis' actions amount

and states that "Wyeth has a present intention

REDACTED

Wyeth relies on the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, for its claim for declaratory relief. Id. at ¶ 6.

REDACTED -

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3. Cordis' Motion to Dismiss or Stay the Federal Court Action

On November 16, 2006, Cordis moved to dismiss the Federal Court Action for lack of subject matter jurisdiction, or in the alternative, to dismiss or stay the case in favor of Cordis' Court of Chancery Action. Exhibit 3. The motion to dismiss is based on the fact there is no subject matter jurisdiction in the Federal Court as both Wyeth and Cordis are citizens of New Jersey. Id. at 8-13. Alternatively, Cordis has moved the Federal Court to dismiss or stay in light of the Supreme Court precedence that strongly cautions federal courts from exercising their discretionary jurisdiction over declaratory judgment cases where no federal legal question is implicated and there is a pending case in state court. Id. at 14-20. Currently, Wyeth is taking jurisdictional discovery and its answering brief is due on February 12. Cordis' reply brief is due February 20.

L Cordis' Court of Chancery Action

The day after Wyeth filed suit in Federal Court and within six and one-half hours of receiving an unredacted version of Wyeth's complaint, Cordis filed an action for declaratory judgment and specific performance in the Court of Chancery. See Cordis Compl. Wyeth's attorneys refused to accept service and Cordis served Wyeth using a process server on November 1. Exhibit 15.

In the Court of Chancery Action, Cordis seeks an order:

REDACTED

REDACTED

\$ directing Wyeth specifically to

perform its obligations under the Agreement; and declaring that Cordis is not in breach or material breach of its obligations under this Agreement or that, if any breach has occurred, it has been cured. Cordis Compl. at Prayer for Relief.

Cordis' Court of Chancery complaint has subsequently been amended ("Amended Cordis Complaint") to seek specific performance requiring Wyeth to take certain steps to ensure

Am. Cordis Compl. at ¶ 53-56, ¶

(h), (j).

III. ARGUMENT

A. The Court of Chancery is the Proper Venue for this Dispute

Cordis brought this suit in Court of Chancery as contemplated under the Agreement. The parties agreed in 1999 to the jurisdiction of the state courts of the state of Delaware (Exhibit 1 at Section 13.7) and Wyeth is a Delaware corporation. Unlike the Federal Court Action, there is no dispute that the Court of Chancery has jurisdiction over this case and Wyeth has not disputed that jurisdiction. In contrast, as will be explained below, Cordis is challenging the subject matter jurisdiction of the Federal Court due to a lack of diversity.

In addition, Cordis brought this case in the Court of Chancery because of the Court's special expertise in resolving corporate conflicts implicating contract law issues that underlie the dispute between the parties in this case. There is no federal legal question raised in this case. St. Clair Intellectual Prop. Consultant, Inc. v. Mirage Sys., Inc., 419 F. Supp. 2d 620, 624 (D. Del. 2006) (dismissing because, inter alia, "state court is a better forum for consideration of state law contract issues."); U.S. Surgical Corp. v. Litvack, 1999 WL 33220034 at *4 (D. Del. Dec. 30, 1999)¹ ("it is important to note that the governing law in this case is not federal law."); American Home Assurance Co. v. Church of Bible Understanding, 2004 WL 1964906 at *4 (E.D. Pa. Aug. 16, 2004) ("This case presents only issues of state worker's compensation and contract law and does not implicate federal law.").

¹ Copies of all unreported decisions are included in a Compendium of Unreported Decisions that has been filed contemporaneously herewith.

Wyeth's cynical manipulation of the litigation process to ensure that it was first filed in Federal Court should not deprive Cordis of its choice of proper venue, the Court of Chancery, to most efficiently and fairly resolve this dispute.

Wyeth's Motion Fails to Satisfy the McWane Doctrine В.

Wyeth's motion to dismiss or stay Cordis' Court of Chancery Action is premised entirely on the doctrine that a court may, in the exercise of its discretion, dismiss or stay an action pending before it in favor of an action pending in another jurisdiction. The doctrine is based on the decision in McWane Cast Iron Pipe Corp. v. McDowell-Wellman Eng'g. Co., 263 A.2d 281 (Del. Supr. 1970), where the Court held that a court can dismiss or stay if (1) "there is a prior action pending elsewhere, (2) in a court capable of doing prompt and complete justice, (3) involving the same parties and the same issues." Id. at 283.

Wyeth's motion to dismiss or stay this action should be denied because it cannot satisfy two of the three prongs of the McWane test. First, Wyeth's Federal Court Action is not a "prior action." While it was technically filed before Cordis' Court of Chancery complaint, well established case law holds that actions filed close in time, especially as here where the first filer manipulates the system in a race to the courthouse, are deemed to be contemporaneously filed. Under those circumstances, courts have consistently declined to stay or dismiss under the McWane analysis.

Second, the Federal Court is not "capable of doing prompt and complete justice." Cordis has moved to dismiss Wyeth's Federal Court Action based on the lack of subject matter jurisdiction. In addition, even if the Federal Court has subject matter jurisdiction, Cordis has asked the Federal Court to abstain from assuming jurisdiction over this case, a declaratory judgment action where the dispute does not implicate federal law. If this Court does not deny

Wyeth's motion based on the fact that these cases were contemporaneously filed, it should defer ruling on this motion until the federal court has decided Cordis' motion to dismiss that case.

> Cordis' Court of Chancery Action Was Filed ì, Contemporaneously with Wyeth's Federal Court Action

According to McWane, a stay or dismissal of a case can be warranted if "there is a prior action pending elsewhere." McWane, 263 A.2d at 283. Under the McWane doctrine, a Delaware court typically will defer to a first-filed action in another forum. Rapoport v. Litig. Trust of MDIP Inc., 2005 WL 3277911 at *2 (Del. Ch. Nov. 23, 2005).

If actions are contemporaneously filed, however, Delaware courts do not defer to the other forum and will instead evaluate a motion for stay or dismissal under the traditional forum non conveniens framework, without regard to the deference shown a first-filed case under McWane. Id. Wyeth has not argued that the case should be stayed or dismissed under a forum non conveniens theory. To the contrary, in the Agreement with Cordis, Wyeth has consented to the jurisdiction of the Delaware State Court system. Exhibit 1 at §13.7. Thus, if it fails to meet the McWane test, its motion to stay or dismiss must fail.

Wyeth's Federal Court Action does not get the benefit of the McWane deference since Wyeth's complaint and Cordis' complaint were filed contemporaneously. The determination of whether an action was first-filed and thus entitled to the McWane deference is not controlled by a mechanical, strictly chronological approach. Rather

> [t]he determination of which action was filed first is a question of fact determined by reference to the underlying procedural facts. The Court, however, does not make that determination mechanically or using a bright-line test. Rather, this Court's complementary objectives of discouraging both forum shopping and contrived races to the courthouse require a more nuanced analysis. Rapoport at *2.

Just because Wyeth won the race to the courthouse doesn't mean that Wyeth is entitled to the deference set forth in the McWane doctrine.

> [T]he McWane doctrine does not denude a trial court of all discretion simply based on the fact that one party won a filing race in a photo-finish. Rather, the Delaware courts have recognized that there are situations where actions should be considered to have been filed contemporaneously.

In to IBP Shareholders Litig., 2001 WL 406292 at *7 (Del. Ch. Apr. 18, 2001); see also Friedman v, Alcatel Alsthom, 752 A.2d 544, 552 (Del. Ch. 1999) (refusing to apply McWane deference where New York suit filed only "several hours" before Delaware suit); Texas Instruments, Inc. v. Cyrix Corp., 1994 WL 96983 (Del. Ch. Mar. 22, 1994) (refusing to apply McWane deference because the mere fact that plaintiff won the race to the courthouse by five hours "should not, without more, impose upon the defendant the significant burden of proving inconvenience and hardship"); Azurix Corp. v. Synagro Techs., 2000 WL 193117 at *3 (Del. Ch. Feb. 3, 2000) ("Since the difference in time of filing is so close, it is fair to treat the competing actions as contemporaneously filed. Support for my finding is borne out of this Court's desire to avoid rewarding the winner of a race to the courthouse.").

Wyeth filed its complaint in Federal Court at 3:33 p.m. on October 26,

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Wyeth relies heavily on the fact that "Cordis agreed to accept service of the Federal complaint on October 27, 2006, before [the Court of Chancery Action] was filed." Wyeth Br. at 1. That hardly means these actions were not contemporaneous. Moreover, Wyeth fails to mention that it refused to provide a copy of the unredacted complaint unless Cordis

agreed to accept service. Exhibit 14. Wyeth provided a copy of the unredacted Federal complaint at 10:00 a.m. on October 27. Id. Cordis' Court of Chancery complaint was filed later that day at 4:24 p.m. Thereafter, Wyeth's attorneys refused to accept service, and forced Cordis to serve using a process server. Exhibit 15.

Wyeth's tactical maneuvering to ensure that it was first filed in Federal Court undermines its reliance on the deference provided such actions under the McWane doctrine.

> It is ... well known that this Court takes a rather dim view of "tactical maneuvers and improper manipulation of the litigation process by parties who seek to invoke the principles of comity and efficiency underlying the McWane doctrine." Rapoport, 2005 WL 3277911 at *4.

Similar fact patterns have led Delaware courts to deny the first filed action the benefit of the McWane deference. In In re IBP Shareholders Litig., 2001 WL 406292 (Del. Ch. Apr. 18, 2001), a class-action suit was pending in Chancery challenging a merger agreement involving IBP and Tyson Foods. Tyson announced at the very end of the business day that it was withdrawing from the merger agreement and that it had filed suit against IBP in Arkansas. Within five business hours, IBP brought cross-claims against Tyson in the Chancery action. Tyson then moved in Chancery to dismiss or stay the cross-claims in favor of the Arkansas suit, arguing that it had "won the race to the courthouse fair and square." Id. at *7.

The Court of Chancery denied Tyson's motion, observing that Tyson was the first to file only

> because it did not give its contractual partner any prior notice of termination. Tyson did so at a time when it was otherwise acting as if the Merger process was ongoing. There is nothing inherently wrong with this tactic in the rough and tumble commercial world, but those who use it should not expect an insurmountable advantage if their scorned partner is able to file an action within five business hours.

Id. at *7-8 (emphasis added) ("For this very reason, the kind of jockeying for position' that Tyson engaged in has been an important factor in Delaware decisions which have denied 'firstfiled' status to such suits."")

In Williams Gas Supply Co. v. Apache Corp., 1991 WL 18091 at *2 (Del. Super 1991), Williams filed in Delaware Superior Court despite ongoing settlement negotiations with Apache. Williams filed suit after its representatives assured Apache that another settlement meeting would be productive. Apache had withheld filing its own suit based on those assurances, but two weeks later did file in Colorado. In response to Apache's motion to dismiss the Delaware suit, the court found that

> It is apparent from the record that [defendant] intended to file suit against [plaintiff] in Colorado but declined to do so in favor of further negotiations. Apparently, the defendant first learned that the negotiations were terminated by receiving notice of the suit filed against it in this State.

Id. (emphasis added). The Court held that "[b]ecause the defendant's good faith should not be punished," Williams first filed action "should not be awarded the deference owed to first filed suits." Id.; see also Rapoport, 2005 WL 3277911 at *4 ("The Court will neither reward the winner of a race to the courthouse nor the manipulator of the litigation process by affording them first-filed status and imposing the accompanying heavy burden on the opposing party to defeat their choice of forum.").

Here, Wyeth won the race to the courthouse by sharp practice. The facts in this cases are consistent with the cases that refuse to grant a deference under McWane to a first filed case. See IBP, Williams, Rapoport, supra. Since Wyeth's Federal Court Action is not entitled to the deference accorded a first filed suit, its motion should be denied.

2. The Federal Court is Incapable of Doing Prompt and Complete Justice

Even if the Wyeth complaint is afforded first-filed status, Wyeth's motion to dismiss or stay should still be denied because the Federal Court Action does not satisfy another prong of the McWane analysis, in particular, the requirement that the prior action be pending "in a Court capable of doing prompt and complete justice." McWane, 263 A.2d at 283. The Federal District Court does not have subject matter jurisdiction over Wyeth's Federal Court Action because there is no diversity between the parties as of the pertinent time for the jurisdictional analysis, i.e., October 26, 2006, the date the Federal complaint was filed. Exhibit 3 at 8-13.

Despite the fact that the Federal Court, not this Court, must decide the question of federal subject matter jurisdiction, Wyeth spends much of its opening brief arguing that Cordis' principal place of business is Miami, relying on prior pleadings in which Cordis has pled that its principal place of business is in Florida. Wyeth Br. at 10-11. In fact, these pleadings are irrelevant to the Federal Court's analysis of whether it has subject matter jurisdiction over the matter. The Third Circuit has unequivocally rejected Wyeth's method of "collecting an array of pleadings filed by "Cordis and contending that representations made in those pleadings "provide valuable evidence indicating where [Cordis'] representatives believe the corporation's principal place of business to be." Mennen Co. v. Atlantic Mut. Ins. Co., 147 F.3d 287, 293 (3d Cir. 1998) ("We do not find that these prior Federal pleadings have evidentiary value for the purpose of assessing where Federal's principal place of business is located."); see also, Creaciones Con Idea, S.A. de C.V. v. Mashregbank PSC, 232 F.3d 79, 82 (2d Cir. 2000) ("The defendant's assertions about its corporate citizenship in unrelated cases therefore could not preclude either the defendant from arguing, or the district court from concluding, that diversity jurisdiction was absent in this case.").

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October 2006, the time when the complaint was filed. In conducting its analysis, the Federal Court will apply the Third Circuit's "center of corporate activities" test, first articulated in Kelly v. U.S. Steel Corp., 284 F.2d 850 (3d Cir. 1960). In Kelly, the Third Circuit found the principal place of business of U.S. Steel Corp. to be Pennsylvania because it was "the headquarters of day-to-day corporate activit[ies] and management." Id. at 854. The Court's analysis was driven principally by the fact that the majority of high level operating executives, including the Operation Policy Committee, were located in Pennsylvania. Factors such as location of employees and physical facilities were considered to be "of lesser importance." Id.; see also Mennen Co., 147 F.3d at 291; Grand Union Supermarkets of the Virgin Islands, Inc. v. H.E. Lockhart Mgmt., Inc., 316 F.3d 408, 411 (3d Cir. 2003); Quaker State Dyeing & Finishing Co. v. ITT Terryphone Corp., 461 F.2d 1140, 1143 (3d Cir. 1972) ("The most significant factor upon which Kelly depends is the headquarters of the day to day corporate activities and management decisions.").

As Cordis has argued to the Federal Court, the <u>Kelly</u> test requires a finding that Cordis' principal place of business is in New Jersey. Exhibit 3 at 11-13.

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These are the issues on which the diversity issue will be decided and, by its actions. Wyeth has acknowledged that they are serious ones on which issue is fairly joined. If prior pleadings answered the question whether there was diversity between the parties, Wyeth would have responded to Cordis' motion to dismiss or stay in the Federal Court Action with the arguments it sets forth in its opening brief here. However, Wyeth did not file such a brief. Instead, it sought and obtained a continuance of the due date for its answering brief to Cordis' motion to dismiss or stay in the Federal Court Action so that it could take jurisdictional discovery. Exhibit 17. Wyeth has propounded extensive document discovery and has noticed fourteen different topics of deposition discovery under F.R.C.P., Rule 30(b)(6), along with the deposition of Rick Anderson, Cordis' Worldwide Franchise Chairman. Exhibits 18 and 19. After it conducts the discovery it has requested, Wyeth will file its responding brief on February 12. Cordis will respond on February 20.

Quite apart from the diversity question, Cordis has also moved, in the alternative, for the Federal Court to stay or dismiss the Federal Court Action in light of the well-established precedent against a Federal Court exercising its jurisdiction over a declaratory judgment action that does not implicate federal law. Id. at 14-20. See Brillhart v. Excess Ins. Co. of America, 316 U.S. 491, 495 (1942); Terra Nova Ins. Co. v. 900 Bar, Inc., 887 F.2d 1213, 1222-24 (3d Cir. 1989). As Cordis has argued, the federal courts have broad discretion whether to accept actions that seek declaratory relief and, in the ordinary course, should decline to exercise such jurisdiction when, as here, the case raises solely issues of state law capable of being resolved in state court.

If the Federal Court rules in Cordis' favor on either ground of its motion, it will dismiss or stay the Federal Court Action. Such a ruling will mean that the Federal Court is not "a court capable of doing prompt and complete justice," McWane, 263 A.2d at 283, and provide a further ground for this Court to deny Wyeth's current motion. Accordingly, in the event this Court decides to give Wyeth the benefit of the first-filed rule, Cordis respectfully requests that the Court defer ruling on this motion until the Federal Court has the opportunity to decide Cordis' motion to dismiss or stay.

CONCLUSION

For the reasons set forth above, this Court should deny Wyeth's motion to dismiss or in the alternative to stay this action.

Dated: January 11, 2007

ASRBY & GEDDES

/s/ Richard L. Renck (#3893)

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EXHIBIT 20

EFiled: Jan 31 2007 5:50PN Transaction ID 13658298

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE IN AND FOR NEW CASTLE COUNTY

CORDIS CORPORATION,)	
Plaintiff,)	
Vs.)	C.A. No. 2504-N
WYETH and WYETH PHARMACEUTICALS DIVISION,)	REDACTED VERSION
Defendants.)	

DEFENDANT WYETH'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO STAY THIS ACTION

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INTRODUCTION

Document 35-2

As set forth in Wyeth's opening brief ("Wyeth Br."), this action is a commercial dispute between two parties, Cordis and Wyeth, that signed a binding License Agreement in which they agreed to resolve any disputes between them relating to that Agreement in either the United States District Court for the District of Delaware or the state courts of Delaware. (License Agreement, § 13.7, Ex. 1 to Cordis's Brief in Opposition.) When a dispute arose, Wyeth filed a complaint in the Delaware federal court, exactly as contemplated by the Agreement. The next day, Cordis filed a second, duplicative action in this Court. On its face, Cordis's Chancery complaint was purely reactive: it asked only for a declaratory judgment that none of the claims asserted by Wyeth in the Federal Action was valid. Cordis's second-filed complaint is blatant forum shopping that is contrary to its contractual obligation to litigate in the Delaware federal court. It is also a transparent effort by Cordis to escape from the federal forum in which there are currently pending numerous other cases involving the Cordis stents at issue here.

Cordis's Brief in Opposition ("Opp.") admits, as it must, that the parties accepted the jurisdiction of the Delaware federal court

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(Opp. at 4.) Likewise, Cordis's

Throughout this reply brief, the term "Wyeth" refers to both Wyeth and Wyeth Pharmaceuticals. As discussed in the opening brief, although the Chancery Complaint in this action names Wyeth Pharmaceuticals Division as a defendant. Wyeth Pharmaceuticals Division is not a separate corporate entity, but an unincorporated division of defendant Wyeth. (Wyeth Br. at 4 n.4.)

Chancery Complaint admits, as it must, that the Federal Complaint was filed first and that Cordis's Chancery Complaint was filed in direct response to the Federal Complaint. (Chancery Compl. ¶¶ 4, 40; Am. Chancery Compl. ¶¶ 4, 41.) Where, as here, the parties expressly agreed to a Delaware federal forum, and a proper complaint in that court was indisputably filed first in time, there are no legal or equitable reasons to overturn that choice of forum.

FACTS

Cordis's Opposition contains a lengthy recitation of the so-called "facts." (Opp. at 3-7.) Most are irrelevant to the narrow matter at issue here, and many are inaccurate. Wyeth does not believe that this is the time or place to argue the merits of this dispute, as Cordis attempts at length to do. Wyeth's Motion to Dismiss is based on a single narrow issue of law -- the application of Delaware's "first-filed" rule. The whole point of the Motion is that the merits of this dispute should be resolved in the first-filed Federal Action, not in Chancery Court. Moreover, regardless of where the merits are resolved, they should not be addressed in a motion to dismiss of this type. For those reasons, Wyeth will neither address nor rebut Cordis's arguments on the merits of the dispute, other than to say that, at the appropriate time and place, Wyeth will demonstrate that Cordis has repeatedly and materially breached the License Agreement, as asserted in Wyeth's Federal Complaint.

In addition to arguing the merits of Wyeth's claims against Cordis, Cordis's Opposition is replete with conclusory, unsupported allegations of misconduct by Wyeth.² This is a diversionary tactic, intended to shift attention away from the merits of Wyeth's motion and the most relevant issues, such as the forum provision of the License Agreement and Delaware's "first-filed" rule.

Document 35-2

First, Cordis claims that Wyeth improperly "manipulat[ed]" "the negotiation process" so that it could "win the 'race to the courthouse." (Opp. at 13; see id. at 15 ("Wyeth won the race to the courthouse by sharp practice"); id. 7, 11.) In fact, the evidence shows that, over a period of many months, Wyeth repeatedly warned Cordis that it was in breach of the Agreement and that, if the breaches were not cured, Wyeth would sue. In the April 14, 2006 letter cited by Cordis (Opp. at 5-7 & Cordis Ex. 2) -sent more than six months before Wyeth filed the Federal Action -- Wyeth asserted that Cordis was "in material breach of its obligations under the [License] Agreement." (Opp. at Cordis Ex. 2, at 1.) In the "Conclusion" to the letter, Wyeth plainly warned that if the breaches were not corrected. Wyeth would pursue all available remedies.³

² See, e.g., Opp. at 5 (asserting that Wyeth's allegations are "pretextual"); id. at 8 (alleging that Wyeth's counsel failed to show "professional courtesy"); id. at 9 (same); id. at 11 ("Wyeth's cynical manipulation of the process"); id. (Wyeth "manipulates the system"); id. at 13 ("Wyeth's manipulation of the negotiation process"); id. at 13-14 (allegations of wrongdoing concerning service of the complaints); id. at 14 ("Wyeth's tactical maneuvering"); id. at 15 (Wyeth is a "manipulator of the litigation process"); id. at 15 (alleging that Wyeth has engaged in "sharp practice").

³ Wyeth stated: "Should Cordis fail to take the actions requested in this letter, Wyeth reserves all rights it has under the Agreement and otherwise, including, without limitation, REDACTED (Continued...)

By letter dated July 27, 2006, Wyeth recited again in detail numerous breaches of the License Agreement and demanded that Cordis

Wyeth demanded Cordis's "immediate REDACTED cooperation in seeking to mitigate the harm Wyeth has suffered and continues to suffer as a result of Cordis's repeated failures to abide by its contractual obligations." (Exhibit A, attached hereto.) When Cordis refused that request, Wyeth sent at least two additional letters, dated August 11 and September 8, 2006, asserting breaches and indicating that it might take action.4

Dissatisfied with Cordis's response, Wyeth agreed nonetheless to make another effort to resolve the disputes in a face-to-face meeting on October 26, 2006. When the parties were still unable to reach agreement at that meeting, Wyeth filed suit. That is hardly a "manipulation" of the process. Wyeth gave Cordis written notice of its breaches more than six months before filing suit. It attempted to resolve the disputes amicably; but when those efforts failed, it did what any aggrieved party has a right to do. It filed suit in a forum that both parties had earlier agreed in writing was appropriate.

There is no evidence of a "race to the courthouse." In fact, Cordis claims that it had no inkling that litigation was imminent and thus, it had no plans to sue. According to

^{(...} continued.)

⁽Opp. at Cordis Ex. 2, at 4.) A reservation of rights REDACTED such as this plainly conveys the notion that litigation is being contemplated.

⁴ See letter dated August 11, 2006, from Theodore R. Koziol (Wyeth) to Eric Harris (Cordis) (Exhibit B, attached hereto); letter dated September 8, 2006, from Theodore R. Koziol (Wyeth) to Eric Harris (Cordis) (Exhibit C, attached hereto).

Cordis,

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The only "race" began after Cordis learned that it had been sued in Delaware federal court. In reaction to the federal suit, Cordis hastily prepared a Chancery Court complaint that included no claims for affirmative relief but instead asked this Court to find a negative, i.e., to issue a declaratory judgment that Cordis had not breached any of the relevant provisions of the License Agreement. It was 20 days later, on November 16, 2006, when Cordis filed an Amended Complaint in this Court, asserting for the first time a single claim for affirmative relief. (Am. Chancery Compl. ¶¶ 43-48, 57-59.) But even that claim is facially inadequate: it asserts a breach of contract based on events that Cordis alleges will occur at the end of 2008, which is nearly two years from now. (See id. ¶ 44.) Based on (i) the absence of any claim for affirmative relief in the Chancery Complaint, (ii) the long delay before the filing of the Amended Complaint, and (iii) Cordis's concession that it came to the October 26, 2006 meeting without any plan to litigate, it is apparent that this Chancery action was initiated solely in reaction to Wyeth's Federal Complaint.

In a further effort to muddy the waters, Cordis claims that Wyeth acted improperly by "refus[ing] to provide Cordis' attorneys with an unredacted version of the [federal] complaint unless Cordis agreed to accept service" of it (Opp. at 2, 8) and by refusing to accept service of the Chancery complaint (Opp. at 9). These allegations are

unsupported, irrelevant, and inaccurate. Each of these allegations is discussed in detail in the Affidavit of Jack Blumenfeld, counsel for Wyeth, filed contemporaneously herewith. (See Blumenfeld Aff.) As Mr. Blumenfeld's Affidavit demonstrates, Wyeth provided an unredacted copy of the Federal Complaint to Cordis on the morning of October 27, approximately 30 minutes after Cordis had requested it; and Wyeth did so unconditionally, without demanding or receiving anything in return. (Blumenfeld Aff. ¶¶ 3-5.) Moreover, and contrary to Cordis's contention, Wyeth never refused to accept service of the Chancery complaint. (Id. at ¶¶ 7-9.)

Finally, Cordis asserts as a "fact" that the "timing and substance of Wyeth's allegations" in the Federal Action "reveal its pretextual nature." (Opp. at 5.) According to Cordis, the Delaware Federal Action was brought as "retaliat[ion]" for a patent infringement suit filed in July 2006 in the Eastern District of Texas, Alza Corporation v. Wyeth, No. 9:06-c.v.-156 (E.D. Tex., filed July 26, 2006). (Id.) Cordis's allegation is unsupported and irrelevant. Significantly, Cordis never even mentions it in the Argument section of the Opposition. The Alza litigation is a patent infringement action involving an anti-depressant drug (EFFEXOR XR®) brought by a company (Alza Corporation) present in neither this action nor the Federal Action. That litigation has no connection with Cordis, with Cordis's citizenship, with the License Agreement, or with Cypher stents. In short, the Alza litigation and this litigation involve separate issues and parties; and each one must stand or fall on its own merits.⁵

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ARGUMENT

In its effort to defeat Wyeth's choice of a Delaware federal forum, Cordis advances two legal arguments. Both are baseless.

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First, Cordis asserts that this Court should ignore Delaware's "first-filed" rule because Wyeth allegedly "manipulated" the "race to the courthouse," or because Wyeth allegedly engaged in "sharp practice" when it served the Federal Complaint. These contentions are unsupported by any evidence and refuted by the case law.

Second, Cordis claims that the Federal Court is "not capable of resolving this dispute" because it lacks subject matter jurisdiction. (Opp. at 1.) But as even Cordis acknowledges, the question of federal subject matter jurisdiction can only be decided by Chief Judge Robinson, not by this Court. Thus, Cordis concedes that if this Court follows the "first-filed" rule and rejects Cordis's first contention, it should "defer ruling on [Wyeth's] motion until the Federal Court has the opportunity to decide Cordis's motion to dismiss or stay" the Federal Action. (Opp. at 19; see also id. at 1 ("Alternatively, [this Court] can await the federal court's resolution of the jurisdictional question before" determining whether to dismiss this action.).) Wyeth believes that there

(... continued.)

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is no reason to delay resolution of this motion. In fact, case law supports this Court's authority to issue stays notwithstanding pending motions to dismiss on jurisdictional grounds in the court of first filing.⁶

Document 35-2

I. This Second-Filed Action Should Be Dismissed or Staved Under Delaware's "First-Filed" Rule.

As discussed in the opening brief, beginning with the seminal decision by the Delaware Supreme Court in McWane, Delaware courts have consistently held that, "as a general rule, litigation should be confined to the forum in which it is first commenced, and a defendant should not be permitted to defeat the plaintiff's choice of forum in a pending suit by commencing litigation involving the same cause of action in another jurisdiction of its own choosing." McWane Cast Iron Pipe Corp. v. McDowell-Wellman Eng'g Co., Del. Supr., 263 A.2d 281, 283 (1970). In its opening brief, Wyeth cited ten Delaware state court cases that have applied the McWane factors to stay or dismiss a second-filed action. (See Wyeth Br. at 12-18.) Cordis did not mention -- much less attempt to distinguish -- a single one of those decisions in its Opposition.

⁶ See, e.g., Gen. Video Corp. v. Kertesz, No. 1922-N, 2006 WL 2051023, at *4-5 (Del. Ch. July 19, 2006) (issuing a stay in favor of previously filed actions in Texas state and federal courts -- although motions to dismiss for lack of personal jurisdiction were pending in both Texas actions -- and explaining that the Court would evaluate whether to lift the stay in the event that the first-filed actions were dismissed on jurisdictional grounds).

⁷ Abbey v. Skokos, No. 2207-N, 2006 WL 2987006, at *2 (Del. Ch. Oct. 10, 2006); Gen. Video Corp. v. Kertesz, No. 1922-N, 2006 WL 2051023, at *3 (Del. Ch. July 19, 2006); In re Westell Techs., No. 18533, 2001 WL 755134, at *2-3 (Del. Ch. June 28, 2001); Welbilt Corp. v. Trane Co., No. 17876, 2000 WL 1742053, at *3 (Del. Ch. Nov. 17, 2000); Visual Edge Sys., Inc. v. Takefman, No. 17472, 2000 WL 193107, at *4 (Del. Ch. Jan. 31, 2000); Corwin v. Silverman, No. 16347, 1999 WL 499456, at *4-5 (Del. Ch. (Continued...)

Equally telling is the fact that Cordis barely mentioned the most salient facts supporting application of the first-filed rule in this action. First and foremost is the fact that Cordis, a sophisticated party advised by counsel, negotiated and signed an Agreement in which it expressly consented to the jurisdiction of the Delaware federal court to resolve disputes arising under that Agreement. Under those circumstances, Cordis cannot possibly claim hardship or surprise based on the fact that it was sued in Delaware federal court.

Second, Wyeth's Federal Action was in fact the "first-filed" of the two complaints. The term "first-filed" refers to which complaint was filed first in time. Here, it is undisputed that Wyeth filed its Federal Complaint on the afternoon of October 26, 2006, and Cordis filed its Chancery Complaint more than 24 hours later, i.e., on the afternoon of October 27, 2006. Although Cordis repeatedly attempts to characterize the two complaints as filed "contemporaneously," that description is no more accurate than saying that sunrise and sunset on the same day are "contemporaneous."

Third, there are no possible grounds on which Cordis can claim hardship based on Wyeth's choice of a federal forum. Unlike many other disputes over the application of

^{(...} continued.)

June 30, 1999); Dura Pharms., Inc. v. Scandipharm, Inc., Del. Ch., 713 A.2d 925, 929 (1998); In Matter of Application of Advanced Drivers Educ. Prods. & Training, Inc., No. 14905, 1996 WL 487940, at *5 (Del. Ch. Aug. 16, 1996); FWM Corp. v. VKK Corp., No. 12485, 1992 WL 87327, at *1-2 (Del. Ch. Apr. 27, 1992); Transamerica Corp. v. Reliance Ins. Co. of Illinois, No. 94C-10-221, 1995 WL 1312656, at *5 (Del. Super. Ct. Aug. 30, 1995).

Cordis concedes the point, stating that Wyeth's Federal Court Action "was technically filed before Cordis' Court of Chancery Complaint. . . ." (Opp. at 11.)

the "first-filed" rule, here the two actions are pending in courthouses located a few blocks from each other. Each courthouse is equally convenient to the parties and the witnesses. If anything, the broader subpoena power of the federal court may make it more likely that all relevant information and witnesses (including those from neighboring New Jersey) are available for the resolution of this action.

Fourth, although Cordis claims that this Court is the more "appropriate court for the dispute to be resolved" (Opp. at 2), Cordis has failed even to mention the fact -prominently addressed in Wyeth's opening brief -- that the judge assigned to Wyeth's
Federal Action already has extensive experience with litigation involving stents,
including numerous cases involving the Cordis Cypher stent at issue here. (See Wyeth
Br. at 12 n.14.) Moreover, Cordis's claim that this Court has "the required expertise in
state contractual law" (Opp. at 2) ignores the fact that the "state contractual law" at issue
here is New Jersey state contractual law, not Delaware law. That fact, too, was
prominently mentioned in Wyeth's opening brief but is ignored by Cordis. (See Wyeth
Br. at 18.) With respect, the Delaware federal court is as capable of applying the law of
New Jersey as any other Delaware court.

Cordis has ignored or failed to address most of these key factual points that are unique to this case. Instead, Cordis cites a handful of decisions in which Delaware courts have found, under narrow circumstances not applicable here, that competing complaints filed very close in time in geographically distant forums can sometimes be deemed "contemporaneously filed" for purposes of the *McWane* rule. None of those cases even remotely resembles this one. Moreover, Cordis has failed to address at all the one

Delaware case on the "contemporaneously filed" issue that is directly applicable here, even though Wyeth highlighted that case in its opening brief. (See Wyeth Br. at 14-15, citing Dura Pharms., Inc. v. Scandipharm, Inc., Del. Ch., 713 A.2d 925 (1998).)

In Dura, one party to a contract sued its partner in Alabama. On the next business day, the Alabama defendant responded with a similar suit in this court. Even though the two suits were filed close in time, the Delaware court applied the McWane rule and stayed the second-filed Delaware action. It cited several important factors that are also relevant here. The Delaware court noted there were no "special circumstances" present in the case. 713 A.2d at 927. The first-filed plaintiff's choice of an Alabama forum was not "unusual or unexpected" and was not made "in order to gain an improper advantage." Id. at 931. Moreover, although the contract was governed by Delaware law, the Delaware law issues did not dictate a Delaware forum, as they were not "novel or complex" and did not "implicate[] significant issues of Delaware corporate policy." Id. Thus, the court concluded, "the fact that Delaware law will apply to the contract based claims does not weigh significantly in the analysis." Id.

In addition, and most importantly, the Dura court noted that the Delaware complaint was reactive, not independent: the Delaware plaintiff "made its decision to file suit in reaction to, rather than independently of, news of [the Alabama] filing." Id. at 929. Under those circumstances, there was no true "race to the courthouse." Id. Instead, the reactive complaint was simply a maneuver by the Alabama defendant to deprive the first-filed plaintiff of its choice of forum once litigation had already begun.

Furthermore, the *Dura* court considered but discounted the importance of traditional *forum non conveniens* factors, such as "ease of access to proof and the availability of compulsory process." *Id.* at 931. Although those factors may have weighed in favor of Delaware, the court concluded that they were not sufficiently significant to "overcome *McWane's* strong preference for confining litigation to the jurisdiction in which it is first brought." *Id*.

All of the factors cited in *Dura* lead to the same result urged here, *i.e.*, deference to the first-filed Federal Action. If anything, the grounds favoring the first-filed forum are even stronger here than in *Dura*. Here, the choice of a Delaware federal forum was not "unusual or unexpected," given that Cordis expressly consented in the License Agreement to litigate in the Delaware federal courts. Not only are there no "complex or novel" questions of Delaware law at issue here; there are no questions of Delaware law at all, as the contract is expressly governed by the law of New Jersey. In addition, none of the *forum non conveniens* factors weighs against Wyeth's choice of the Delaware federal forum, because the choice here is between two courthouses that sit a few blocks apart from each other in the same city. To the extent that *forum non conveniens* factors matter at all, they cut in favor of the federal forum, which has broader subpoena powers and years of litigation experience with the same stents at issue here.

Finally, as in *Dura*, there is no evidence of a "race of the courthouse" that deprived Cordis of its chosen venue. Before filing suit, Wyeth gave Cordis well over six months' notice that it would take action if the parties' disputes over the License Agreement could not be amicably resolved.

REDACTED

REDACTED

Wyeth did exactly what it

was entitled to do and what it had been warning Cordis about for six months: it filed suit in a forum chosen by the parties. Wyeth did not "race" to the courthouse. And Cordis, by its own admission, was not "racing" to the courthouse with a complaint that it hoped to file before Wyeth had filed first. Cordis claims not to have known that Wyeth intended to sue until Cordis received a redacted version of the Federal Complaint. The only "race" occurred *after* the Federal Complaint was filed, when Cordis scrambled to cobble together a Chancery complaint that it hoped would deprive Wyeth of its chosen forum. This is not a courthouse "race," but simply an instance of a party filing a *reactive* complaint for the purpose of forum shopping after the fact. As *Dura* plainly holds, a reactive complaint should get no preference under the *McWane* rule, no matter how quickly it is filed.

REDACTED

Although Wyeth plainly conveyed to Cordis its intent to resolve the dispute through litigation if other means failed, Cordis either did not understand, or professes now not to have understood, that fact.

⁹ Cordis does not contend that it had drafted a complaint and intended to sue, but was beaten to the courthouse by Wyeth. To the contrary, Cordis has plainly stated that it did *not* anticipate Wyeth's lawsuit and that it did not have any independent intention to file suit. (Opp. at 7

¹⁰ Under these circumstances, it is readily apparent that Cordis's Delaware complaint was a hastily prepared document, written in reaction to the Federal Complaint and filed for the express purpose of attempting to defeat Wyeth's choice of a Delaware federal forum.

Having ignored *Dura*, Cordis cites several cases that are plainly inapposite. In *In re IBP Shareholders Litigation*, No. 18373, 2001 WL 406292 (Del. Ch. Apr. 18, 2001) (Opp. at 13), there was a true race to the courthouse by parties intent on suing each other. Tyson won the race, filing first in Arkansas, its home state; and IBP filed five hours later in Delaware Chancery Court. The Delaware court refused to stay its proceedings in favor of the first-filed suit, but only because the bulk of the claims in the Arkansas action were covered by an agreement between the parties that specified Delaware as the exclusive forum for their resolution. *Id.* at *1, *5, *8. Thus, far from supporting Cordis or undercutting *McWane*'s preference for the first-filed action, *IBP* merely holds that the parties' forum selection clause should be honored in a close case. Here, Wyeth not only filed first, but it did so in a forum that the parties had expressly agreed was appropriate.

Texas Instruments, Inc. v. Cyrix Corp., No. 13288, 1994 WL 96983 (Del. Ch. Mar. 22, 1994), also cited by Cordis (Opp. at 13), involved another true race to the courthouse in which one party filed a Delaware action five hours before the other party filed in Texas. Even though the Delaware complaint was first-filed, the Delaware court deferred to the second-filed action. The court did so after performing a "conventional forum non conveniens analysis" and finding that the relevant factors "weigh overwhelmingly in favor of the Texas forum, and [Texas Instruments] has identified no factor that weighs in favor of the Delaware forum." Id. at *6. Thus, the Delaware court concluded that nearly all of the employees and witnesses with relevant knowledge were in Texas, not Delaware, id. at *1; and requiring the parties to litigate in Delaware would

have imposed a significant burden of "inconvenience and hardship" on the non-Delaware party. Id. at *4, *6.

That analysis only underscores the weakness of Cordis's position here. Here, Cordis has not shown any evidence of a race to the courthouse, has not identified any "inconvenience or hardship" in litigating in Delaware federal court, has not even attempted to do a forum non conveniens analysis such as the one in Texas Instruments, and has not identified a single factor suggesting that this Court is better positioned to resolve the dispute than the Delaware federal court. 11 More generally, Cordis has not identified any instance in which this Court has refused to follow the McWane rule when the competing, first-filed action was in another Delaware court.

Finally, Cordis's reliance on Rapoport v. The Litigation Trust of MDIP Inc., No. 1035-N, 2005 WL 3277911 (Del. Ch. Nov. 23, 2005) (Opp. at 12, 14), is unavailing. There, the Trust first sued in Delaware and then attempted to abandon Delaware, over the objections of its adversary, in favor of litigation in Ohio. Decrying such tactical

Similarly, Friedman v. Alcatel Alsthom, Del. Ch., 752 A.2d 544 (1999), cited by Cordis (Opp. at 13), involved a true race to the courthouse that was won when one set of shareholder plaintiffs filed suit in New York federal court three hours before another set of shareholder plaintiffs filed in Delaware Chancery court. Using a forum non

conveniens analysis, the Delaware court stayed the second-filed action in favor of the first-filed action. Significantly, the court noted that, even when McWane's presumption does not apply and the analysis is based solely on forum non conveniens, deference should still be given to the first-filed case. Id. at 552 ("Only in a rare case should plaintiff's choice of forum be defeated in favor of a later-filed action in another jurisdiction [I]n order to prevail on a forum non conveniens motion, a defendant must establish, with particularity, that it will be subjected to undue hardship and inconvenience if required to litigate in Delaware," citing Chrysler First Bus. Credit Corp. v. 1500 Locust Ltd., Del. Supr., 669 A.2d 104, 107 (1995).)

maneuvering and forum shopping, the Chancery court required the parties to remain in Delaware, where the litigation first began. See id. at *4. This outcome was further supported by the fact that "the relevant forum non conveniens factors" in the case pointed toward Delaware. Id. at *8. Here, by contrast, Wyeth has maintained its original choice of forum and, as described above, Chancery Court does not offer any advantages over Delaware federal court in terms of convenience to the parties.

The other cases cited by Cordis are equally inapposite. None of them even remotely supports Cordis's claim that the McWane presumption in favor of the first-filed action should be overruled here. 12

¹² In Williams Gas Supply Co. v. Apache Corp., No. 90C-AU-1, 1991 WL 18091, at *2 (Del. Super, Ct. Feb. 12, 1991), the Delaware court deferred to the second-filed action in Colorado, based on evidence of litigation misconduct by the Delaware plaintiff, Williams Gas. The court found that Williams Gas -- despite giving explicit assurances that further negotiation would be productive and after learning that its adversary had already prepared a complaint -- filed a declaratory judgment action in Delaware for the sole purpose of denying its adversary the Colorado forum to which it would otherwise have been entitled. After expressing skepticism about purely declaratory judgment suits because of their potential use as a vehicle for forum shopping, id. at *2, the Delaware court also noted that the traditional forum non conveniens factors in any event favored Colorado. Id. at *3-4. Here, of course, it is Cordis's second-filed suit that was a purely declaratory judgment suit intended to manipulate the forum; and no forum non conveniens factors favor Cordis. In Azurix Corp. v. Synagro Techs., No. 17509, 2000 WL 193117 at *3, *7 (Del. Ch. Feb. 3, 2000), the Delaware court stayed its own proceedings in favor of a Texas action "filed only scant minutes" after the Delaware suit, after determining that the relevant forum non conveniens factors "preponderate[d]" in favor of litigating in Texas. As noted earlier, Cordis's reactive complaint was filed more than one full day after Wyeth's complaint was filed, and the forum non conveniens factors are entirely unhelpful to Cordis here.

The Delaware Federal Court Is Fully Capable of Resolving this Dispute. II.

Cordis also asks this Court to conclude that the Delaware federal district court is "not capable of resolving this dispute," because "it has no subject matter jurisdiction." (Opp. at 1.) Cordis's argument is both misdirected and wrong.

First and foremost, it is for the Federal Court, not this Court, to determine whether there is federal subject matter jurisdiction over Wyeth's Federal Action. Wyeth will make that case to Chief Judge Robinson, not to this Court. However, given Cordis's extended argument on that subject (Opp. at 16-19), a few points are worth noting here.

First, as already stated, Cordis expressly consented in the License Agreement to the jurisdiction of the Delaware federal court for disputes arising during the term of the Agreement. That Agreement was based on the premise that Cordis was a Florida corporation with its principal place of business in Florida, because (i) that is what Cordis had consistently represented about itself, and (ii) that is the only scenario under which the Delaware federal court could have jurisdiction of contractual disputes arising under the Agreement. Although Cordis signed amendments to the Agreement in 2001 and 2005, it never altered its consent to federal jurisdiction. In consenting to litigate in the Delaware federal district court, Cordis has expressly acknowledged that the federal court is competent to resolve disputes arising under the Agreement.

Second, as noted in the opening brief, Cordis has consistently represented to courts throughout the country that it is a Florida corporation with its principal place of business in Florida. (Wyeth Br. at 10 & n.12.) Wyeth cited nine such representations, including one made on October 16, 2006 -- ten days before Wyeth filed the federal

action. 13 In response, Cordis does not deny the representations or even attempt to explain why they were made or how they could possibly be consistent with Cordis's current claim of New Jersey citizenship. Instead, Cordis cites Mennen Co. v. Atlantic Mutual Insurance Co., 147 F.3d 287, 293 (3d Cir. 1998), for the proposition that prior representations by a party and its counsel to courts have no bearing on the question of citizenship for diversity purposes. (Opp. at 16.) Mennen holds no such thing; and it certainly is not a license to litigating parties to misrepresent their citizenship.

Mennen involved a situation in which all of the "empirical facts," id. at 293, concerning the defendant insurer's principal place of business -- including the location of most of its operations and employees, the place where it conducted most of its business operations, the place where it filed its tax returns, etc. -- pointed to New Jersey, id. at 289. Nevertheless, the Mennen plaintiff sought to overcome that evidence by citing two prior instances in which the defendant had stated that its principal place of business was Indiana, not New Jersey. Unlike here, however, in both of those instances, the defendant had corrected its prior representations, telling the courts that they were inaccurate and that the defendant's true place of business was in fact New Jersey, not Indiana. Id. at 293 n.8. The Third Circuit in Mennen held only that a party's prior representations about its principal place of business -- that were inaccurate when made, but were subsequently

¹³ Wyeth Br. at 10 n.12. Since filing the opening brief, Wyeth has discovered a number of other, similar representations made by Cordis in court filings, administrative matters, and contractual agreements. All of this evidence will be presented in due course to Chief Judge Robinson in the Federal Action.

corrected -- have no estoppel effect if they "run contrary to the empirical facts with which the jurisdictional inquiry is concerned." *Id.* at 293.

Mennen is a far cry from the situation here. Unlike in Mennen, Cordis's prior representations about its principal place of business have been consistent and unwavering, and they are also consistent with all of the other empirical facts known about Cordis. Indeed, the brief jurisdictional discovery so far conducted in the Federal Action has disclosed a mountain of evidence about Cordis's operations that strongly supports Cordis's own prior conclusion that its principal place of business is in Florida. In virtually every category of factual information relevant under the leading case for determining principal place of business in the Third Circuit, Kelly v. U.S. Steel Corp., 284 F.2d 850 (3d Cir. 1960), the evidence points to Florida, not New Jersey. At the appropriate time, Wyeth will present that evidence to the federal court and demonstrate that Cordis's newfound claim of New Jersey citizenship was concocted by Cordis to escape the jurisdiction of a court that is already fully familiar with Cordis and its Cypher stent.

Finally, Cordis's reliance on *Brillhart v. Excess Ins. Co. of America*, 316 U.S. 491 (1942), is misplaced. Once again, Cordis has everything backwards. *Brillhart* involved

Contrary to Cordis's suggestion, the fact that Wyeth has sought and obtained jurisdictional discovery in the Federal Action does not give any credence to Cordis's newfound claim of New Jersey citizenship. (Opp. at 18.) Wyeth's discovery requests were necessitated by Cordis's extraordinary claim that its citizenship somehow changed between October 16, 2006, when Cordis represented that its principal place of business was Florida, and October 26, 2006, when Wyeth filed the Federal Action -- only to be told by Cordis that its principal place of business had relocated to New Jersey.

solely declaratory judgment claims, and federal circuit courts have refused to apply Brillhart to suits, such as Wyeth's, that seek damages and injunctive relief, in addition to declaratory relief. See, e.g., Am. Guar. & Liab. Ins. Co. v. Anco Insulations, Inc., 408 F.3d 248, 250-51 nn.8-9 (5th Cir. 2005); Cedar Rapids Cellular Tel., L.P. v. Miller, 280 F.3d 874, 879 (8th Cir. 2002). Here, the only complaint that sought purely declaratory relief was Cordis's reactive complaint filed in this Court on October 27, 2006.

21.

CONCLUSION

For the reasons stated here and in Wyeth's opening brief, the Motion should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on February 20, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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I also certify that copies were caused to be served on February 20, 2007 upon the following in the manner indicated:

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